



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11) Publication number : **0 565 331 A2**

(12)

EUROPEAN PATENT APPLICATION

(21) Application number : 93302662.7

(51) Int. Cl.⁵ : **A61N 5/06**

(22) Date of filing : 05.04.93

(30) Priority : 09.04.92 IL 101547
20.10.92 US 964210

(43) Date of publication of application :
13.10.93 Bulletin 93/41

(84) Designated Contracting States :
AT BE CH DE DK ES FR GB GR IE IT LI LU MC
NL PT SE

(71) Applicant : **ESC Inc**
329 Central Street
Newton, Massachusetts, 02166 (US)

(72) Inventor : **Eckhouse, Shimon**
27 Ester-Rabin Street
Haifa 34987 (IL)

(74) Representative : **Cookson, Barbara Elizabeth**
et al
Titmuss Sainer & Webb, 2 Serjeants' Inn
London EC4Y 1LT (GB)

(54) Therapeutic electromagnetic treatment.

(57) A therapeutic treatment device is disclosed and includes a housing (12) and an incoherent light source (14) such as a flashlamp disposed in the housing. The flashlamp provides a pulsed light output for treatment of external skin disorders. To provide light to the treatment area the housing has an opening that is disposed adjacent a skin treatment area. A reflector (16) is mounted within the housing near the light source to reflect the light to the treatment area. At least one optical filter (18) and an iris (20) are mounted near the opening in the housing. Power to the lamp is provided by a pulse forming circuit that can provide a variable pulse width.

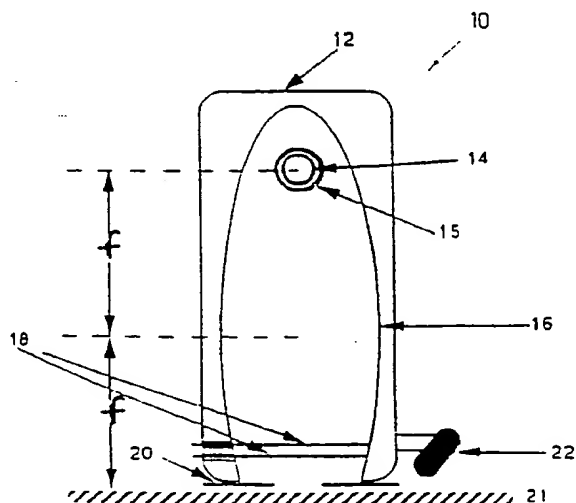


Figure 1

The present invention relates generally to the art of therapeutic electromagnetic treatment and more specifically to a method and apparatus for utilising a spatially extended pulsed light source such as a flash-lamp (flash tube) for such a treatment or, efficiently focusing light from the flashlamp into optical fibres for therapeutic treatment or other applications.

It is known in the prior art to use electromagnetic radiation in medical application for therapeutic uses such as treatment of skin disorders. For example, US-A-4,298,005 (Mutzhas) describes a continuous ultra-violet lamp with cosmetic, photobiological, and photochemical applications. A treatment based on using the UV portion of the spectrum and its photochemical interaction with the skin is described. The power delivered to the skin using Mutzhas' lamp is described as 150W/m², which does not have a significant effect on skin temperature.

In addition to prior art treatment involving UV light, lasers have been used for dermatological procedures, including Argon lasers, CO₂ lasers, Nd(Yag) lasers, Copper vapor lasers, ruby lasers and dye lasers. For example, US-A-4,829,262 (Furumoto), describes a method of constructing a dye laser used in dermatology applications. Two skin conditions which may be treated by laser radiation are external skin irregularities such as local differences in the pigmentation or structure of the skin, and vascular disorders lying deeper under the skin which cause a variety of skin abnormalities including port wine stains, telangiectasias, leg veins and cherry and spider angiomas. Laser treatment of these skin disorders generally includes localised heating of the treatment area by absorption of laser radiation. Heating the skin changes or corrects the skin disorder and causes the full or partial disappearance of the skin abnormality.

Certain external disorders such as pigmented lesions can also be treated by heating the skin very fast to a high enough temperature to evaporate parts of the skin. Deeper-lying vascular disorders are more typically treated by heating the blood to a high enough temperature to cause it to coagulate. The disorder will then eventually disappear. To control the treatment depth a pulsed radiation source is often used. The depth the heat penetrates in the blood vessel is controlled by controlling the pulse width of the radiation source. The absorption and scattering coefficients of the skin also affect the heat penetration. These coefficients are a function of the constituents of skin and the wavelength of the radiation. Specifically, the absorption coefficient of light in the epidermis and dermis tends to be a slowly varying, monotonically decreasing function of wavelength. Thus, the wavelength of the light should be chosen so that the absorption coefficient is optimised for the particular skin condition and vessel size being treated.

The effectiveness of lasers for applications such as tattoo removal and removal of birth and age marks

is diminished because lasers are monochromatic. A laser of a given wavelength may be effectively used to treat a first type of skin pigmentation disorder, but, if the specific wavelength of the laser is not absorbed efficiently by skin having a second type of disorder, it will be ineffective for the second type of skin disorder. Also, lasers are usually complicated, expensive to manufacture, large for the amount of power delivered, unreliable and difficult to maintain.

The wavelength of the light also affects vascular disorder treatment because blood content in the vicinity of the vascular disorders varies, and blood content affects the absorption coefficient of the treatment area. Oxyhemoglobin is the main chromophore which controls the optical properties of blood and has strong absorption bands in the visible region. More particularly, the strongest absorption peak of oxyhemoglobin occurs at 418nm and has a band-width of 60nm. Two additional absorption peaks with lower absorption coefficients occur at 542 and 577nm. The total band-width of these two peaks is on the order of 100nm. Additionally, light in the wavelength range of 500 to 600nm is desirable for the treatment of blood vessel disorders of the skin since it is absorbed by the blood and penetrates through the skin. Longer wavelengths up to 1000nm are also effective since they can penetrate deeper into the skin, heat the surrounding tissue and, if the pulse-width is long enough, contribute to heating the blood vessel by thermal conductivity. Also, longer wavelengths are effective for treatment of larger diameter vessels because the lower absorption coefficient is compensated for by the longer path of light in the vessel.

In addition to being used for treating skin disorders, lasers have been used for invasive medical procedures such as lithotripsy and removal of blood vessel blockage. In such invasive procedures laser light is coupled to optical fibres and delivered through the fibre to the treatment area. In lithotripsy the fibre delivers light from a pulsed laser to a kidney or gallstone and the light interaction with the stone creates a shock wave which pulverises the stone. To remove blood vessel blockage the light is coupled to the blockage by the fibre and disintegrates the blockage. In either case the shortcomings of lasers discussed above with respect to laser skin treatment are present. Accordingly, a treatment device for lithotripsy and blockage removal utilising a flashlamp would be desirable.

To effectively treat an area the light from the source must be focused on the treatment area. Coupling pulsed laser light into optical fibres in medicine is quite common. The prior art describes coupling isotropic incoherent point sources such as CW lamps into small optical fibres. For example, US-A-4,757,431 (Cross, et al.) discloses a method for focusing incoherent point sources with small filaments or an arc lamp with an electrode separation of 2mm

into a small area. Point (or small) sources are relatively easy to focus without large losses in energy because of the small size of the source. Also, US-A-4,022,534 (Kishner) discloses light produced by a flash tube and the collection of only a small portion of the light emitted by the tube into an optical fibre.

However, the large dimension of an extended source such as a flashlamp make it difficult to focus large fractions of its energy into small areas. Coupling into optical fibres is even more difficult since not only must a high energy density be achieved, but the angular distribution of the light has to be such that trapping in the optical fibre can be accomplished. Thus, it is desirable to have a system for coupling the output of a high intensity, extended, pulsed light source into an optical fibre.

In order to solve the technical problems outlined above including the specificity of prior art systems and their technical complexity and expense, the device or system of the present invention is characterised by the provision of pulsed incoherent radiation.

Accordingly, in one embodiment, a wide band electromagnetic radiation source that covers the near UV and the visible portion of the spectrum would be desirable for treatment of external skin and vascular disorders. The overall range of wavelengths of the light source should be sufficient to optimise treatment for any of a number of applications. Such a therapeutic electromagnetic radiation device should also be capable of providing an optimal wavelength range within the overall range for the specific disorder being treated. The intensity of the light should be sufficient to cause the required thermal effect by raising the temperature of the treatment area to the required temperature. Also, the pulse-width should be variable over a wide enough range so as to achieve the optimal penetration depth for each application. Therefore, it is desirable to provide a light source having a wide range of wavelengths, which can be selected according to the required skin treatment, with a controlled pulse-width and a high enough energy density for application to the affected area.

Pulsed non-laser type light sources such as linear flashlamps provide these benefits. The intensity of the emitted light can be made high enough to achieve the required thermal effects. The pulse-width can be varied over a wide range so that control of thermal depth penetration can be accomplished. The typical spectrum covers the visible and ultraviolet range and the optical bands most effective for specific applications can be selected, or enhanced using fluorescent materials. Moreover, non-laser type light sources such as flashlamps are much simpler and easier to manufacture than lasers, are significantly less expensive for the same output power and have the potential of being more efficient and more reliable. They have a wide spectral range that can be optimised for a variety of specific skin treatment applications. These

sources also have a pulse length that can be varied over a wide range which is critical for the different types of skin treatments.

The scope of the invention is defined in the claims and the embodiments outlined below are specific combinations suitable for implementing the invention.

According to a first embodiment of the invention a therapeutic treatment device comprises a housing and an incoherent light source, suitably a flashlamp, operable to provide a pulsed light output for treatment, disposed in the housing. The housing has an opening and is suitable for being disposed adjacent a skin treatment area. A reflector is mounted within the housing proximate the light source, and at least one optical filter is mounted proximate the opening in the housing. An iris is mounted coextensively with the opening. Power to the lamp is provided by a variable pulse width pulse forming circuit. Thus, the treatment device provides controlled density, filtered, pulsed light output through an opening in the housing to a skin area for treatment.

According to a second embodiment of the invention a method of treatment with light energy comprises the steps of providing a high power, pulsed light output from a non-laser, incoherent light source and directing the pulsed light output to a treatment area. The pulse width of the light output is controlled and focused so that the power density of the light is controlled. Also, the light is filtered to control the spectrum of the light.

According to a third embodiment of the invention a coupler comprises an incoherent light source such as a toroidal flashlamp. A reflector is disposed around the incoherent light source and at least one optical fibre or light guide. The fibre has an end disposed within the reflector. This end collects the light from the circular lamp. In a similar coupling configuration fibres may be provided, along with a linear to circular fibre transfer unit disposed to receive light from the light source and provide light to the optical fibres. The reflector has an elliptical cross-section in a plane parallel to the axis of the linear flash tube, and the linear flash tube is located at one focus of the ellipse while the linear to circular transfer unit is located at the other focus of the ellipse.

For a better understanding of the invention, reference is made to the accompanying diagrammatic drawings, in which:

Figure 1 is a cross-sectional view of an incoherent, pulsed light source skin treatment device;

Figure 2 is a side view of the light source of Figure 1;

Figure 3 is a schematic diagram of a pulse forming network with a variable pulse width for use with the skin treatment device of Figures 1 and 2; Figure 4 is a cross-sectional view of a coupler for coupling light from a toroidal flash tube into an

optical fibre with a conical edge;

Figure 5 is a side view of a toroidal flash tube;

Figure 6 is a top view of a toroidal flash tube;

Figure 7 shows the geometry for coupling into a conical section;

Figure 8 is a cross-sectional view of a coupler for coupling light from a toroidal flash tube into an optical fibre with a flat edge;

Figure 9 is a front sectional view of a coupler for coupling light from a linear flash tube into a circular fibre bundle;

Figure 10 is a side sectional view of the coupler of Figure 9;

Figure 11 is a front view of a coupler for coupling light from a linear flash tube into an optical fibre; and

Figure 12 is a front view of a coupler for coupling light from a linear flash tube into a doped optical fibre.

In the various figures, like reference numerals are used to describe like components.

Before explaining at least one embodiment of the invention in detail it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practised or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

Referring now to Figures 1 and 2, cross-sectional and side views of an incoherent, pulsed light source skin treatment device 10 constructed and operated in accordance with the principles of the present invention are shown. The device 10 may be seen to include a housing 12, having an opening therein, a handle 13 (Figure 2 only), a light source 14 having an outer glass tube 15, an elliptical reflector 16, a set of optical filters 18, an iris 20 and a detector 22 (Figure 1 only). Light source 14, which is mounted in housing 12, may be a typical incoherent light source such as a gas filled linear flashlamp Model No. L5568 available from ILC. The spectrum of light emitted by gas filled linear flashlamp 14 depends on current density, type of glass envelope material and gas mixture used in the tube. For large current densities (e.g., 3000 A/cm² or more) the spectrum is similar to a black body radiation spectrum. Typically, most of the energy is emitted in the 300 to 1000nm wavelength range.

To treat a skin (or visible) disorder a required light density on the skin must be delivered. This light density can be achieved with the focusing arrangement shown in Figures 1 and 2. Figure 1 shows a cross-section view of reflector 16, also mounted in housing 12. As shown in Figure 1, the cross-section of reflector 16 in a plane is perpendicular to the axis of flashlamp 14 is an ellipse. Linear flashlamp 14 is located

at one focus of the ellipse and reflector 16 is positioned in such a way that the treatment area of skin 21 is located at the other focus. The arrangement shown is similar to focusing arrangements used with lasers and efficiently couples light from flashlamp 14 to the skin. This arrangement should not, however, be considered limiting. Elliptical reflector 16 may be a metallic reflector, typically polished aluminum which is an easily machinable reflector and has a very high reflectivity in the visible, and the UV range of the spectrum can be used. Other bare or coated metals can also be used for this purpose.

Optical and neutral density filters 18 are mounted in housing 12 near the treatment area and may be moved into the beam or out of the beam to control the spectrum and intensity of the light. Typically, 50 to 100nm band-width filters, as well as low cut-off filters in the visible and ultraviolet portions of the spectrum, are used. In some procedures it is desirable to use most of the spectrum, with only the UV portion being cut off. In other applications, mainly for deeper penetration, it is preferable to use narrower band-widths. The band-width filters and the cut-off filters are readily available commercially.

Glass tube 15 is located coaxially with flashlamp 14 and has fluorescent material deposited on it. Glass tube 15 will typically be used for treatment of coagulation of blood vessels to optimise the energy efficiency of device 10. The fluorescent material can be chosen to absorb the UV portion of the spectrum of flashlamp 14 and generate light in the 500 to 650nm range that is optimised for absorption in the blood. Similar materials are coated on the inner walls of commercial fluorescent lamps. A typical material used to generate "warm" white light in fluorescent lamps has a conversion efficiency of 80%, has a peak emission wavelength of 570nm and has a bandwidth of 70nm and is useful for absorption in blood. The few millisecond decay time of these phosphors is consistent with long pulses that are required for the treatment of blood vessels.

Other shapes or configurations of flashlamp 14 such as circular, helical, short arc and multiple linear flashlamps may be used. Reflector 16 may have other designs such as parabolic or circular reflectors. The light source can also be used without a reflector and the required energy and power density may be achieved by locating light source 14 in close proximity to the treatment area.

Iris 20 is mounted in housing 12 between optical filters 18 and the treatment area and controls the length and the width of the exposed area, i.e. by collimating the output of flashlamp 14. The length of flashlamp 14 controls the maximum length that can be exposed. Typically a 8cm long (arc length) tube will be used and only the central 5cm of the tube is exposed. Using the central 5cm assures a high degree of uniformity of energy density in the exposed skin

area. Thus, in this embodiment the iris 20 (also called a collimator) will enable exposure of skin areas of a maximum length of 5cm. The iris 20 may be closed to provide a minimum exposure length of one millimetre. Similarly, the width of the exposed skin area can be controlled in the range of 1 to 5mm for a 5mm wide flashlamp. Larger exposed areas can be easily achieved by using longer flash tubes or multiple tubes, and smaller exposure areas are obtainable with an iris that more completely collimates the beam. The present invention provides a larger exposure area compared to prior art lasers or point sources and is very effective in the coagulation of blood vessels since blood flow interruption over a longer section of the vessel is more effective in coagulating it. The larger area exposed simultaneously also reduces the required procedure time.

Detector 22 (Figure 1) is mounted outside housing 12 and monitors the light reflected from the skin. Detector 22 combined with optical filters 18 and neutral density filters can be used to achieve a quick estimate of the spectral reflection and absorption coefficients of the skin. This may be carried out at a low energy density level prior to the application of the main treatment pulse. Measurement of the optical properties of the skin prior to the application of the main pulse is useful to determine optimal treatment conditions. As stated above, the wide spectrum of the light emitted from the non-laser type source enables investigation of the skin over a wide spectral range and choice of optimal treatment wavelengths.

In an alternative embodiment, detector 22 or a second detector system may be used for real-time temperature measurement of the skin during its exposure to the pulsed light source. This is useful for skin thermolysis applications with long pulses in which light is absorbed in the epidermis and dermis. When the external portion of the epidermis reaches too high a temperature, permanent scarring of the skin may result. Thus, the temperature of the skin should be measured. This can be realised using infra-red emission of the heated skin, to prevent over-exposure.

A typical real-time detector system would measure the infra-red emission of the skin at two specific wavelengths by using two detectors and filters. The ratio between the signals of the two detectors can be used to estimate the instantaneous skin temperature. The operation of the pulsed light source can be stopped if a preselected skin temperature is reached. This measurement is relatively easy since the temperature threshold for pulsed heating that may cause skin scarring is on the order of 50°C or more, which is easily measurable using infrared emission.

The depth of heat penetration depends on the light absorption and scattering in the different layers of the skin and the thermal properties of the skin. Another important parameter is pulse-width. For a

pulsed light source, the energy of which is absorbed in an infinitesimally thin layer, the depth of heat penetration (d) by thermal conductivity during the pulse can be written as shown in Equation 1:

$$(Eq. 1) \quad d = 4 [k\Delta t/C\rho]^{1/2}$$

where

k = heat conductivity of the material being illuminated;

Δt = the pulse-width of the light pulse;

C = the heat capacity of the material;

ρ = density of the material.

It is clear from Equation 1 that the depth of heat penetration can be controlled by the pulse-width of the light source.

Thus, a variation of pulse-width in the range of 10^{-5} sec to 10^{-1} sec will result in a variation in the thermal penetration by a factor of 100.

Accordingly, the flashlamp 14 provides a pulse width of from 10^{-5} sec to 10^{-1} sec. For treatment of vascular disorders in which coagulation of blood vessels in the skin is the objective the pulse length is chosen to uniformly heat as much of the entire thickness of the vessel as possible to achieve efficient coagulation. Typical blood vessels that need to be treated in the skin have thicknesses in the range of 0.5mm. Thus, the optimal pulse-width, taking into account the thermal properties of blood, is on the order of 100msec. If shorter pulses are used, heat will still be conducted through the blood to cause coagulation, however, the instantaneous temperature of part of the blood in the vessel and surrounding tissue will be higher than the temperature required for coagulation and may cause unwanted damage.

For treatment of external skin disorders in which evaporation of the skin is the objective, a very short pulse-width is used to provide for very shallow thermal penetration of the skin. For example, a 10^{-5} sec pulse will penetrate (by thermal conductivity) a depth of the order of only 5 microns into the skin. Thus, only a thin layer of skin is heated, and a very high, instantaneous temperature is obtained so that the external mark on the skin is evaporated.

Figure 3 shows a variable pulse-width pulse forming circuit comprised of a plurality of individual pulse forming networks (PFN's) that create the variation in pulse-widths of flashlamp 14. The light pulse full width at half maximum (FWHM) of a flashlamp driven by a single element PFN with capacitance C and inductance L is approximately equal to:

$$(Eq.2) \quad \Delta t \approx 2[LC]^{1/2}$$

Flashlamp 14 may be driven by three different PFN's, as shown in Figure 3. The relay contacts R1', R2' and R3' are used to select among three capacitors C1, C2 and C3 that are charged by the high voltage power supply. Relays R1, R2 and R3 are used to select the PFN that will be connected to flashlamp 14. The high voltage switches S1, S2 and S3 are used to discharge the energy stored in the capacitor of the

PFN into flashlamp 14. In one embodiment L1, L2 and L3 have values of 100mH, 1mH and 5mH, respectively, and C1, C2 and C3 have values of 100mF, 1mF and 10mF, respectively.

In addition to the possibility of firing each PFN separately, which generates the basic variability in pulse-width, additional variation can be achieved by firing PFN's sequentially. If, for example, two PFN's having pulse-width Δt_1 and Δt_2 are fired, so that the second PFN is fired after the first pulse has decayed to half of its amplitude, then an effective light pulse-width of this operation of the system will be given by the relation: $\Delta t \approx \Delta t_1 + \Delta t_2$.

The charging power supply typically has a voltage range of 500V to 5kV. The relays should therefore be high voltage relays that can isolate these voltages reliably. The switches S are capable of carrying the current of flashlamp 14 and to isolate the reverse high voltage generated if the PFNs are sequentially fired. Solid-state switches, vacuum switches or gas switches can be used for this purpose.

A simmer power supply (not shown in Figure 3) may be used to keep the flashlamp in a low current conducting mode. Other configurations can be used to achieve pulse-width variation, such as the use of a single PFN and a crowbar switch, or use of a switch with closing and opening capabilities.

Typically, for operation of flashlamp 14 with an electrical pulse-width of 1 to 10msec, a linear electrical energy density input of 100 to 300J/cm can be used. An energy density of 30 to 100J/cm² can be achieved on the skin for a typical flashlamp bore diameter of 5mm. The use of a 500 to 650nm bandwidth transmits 20% of the incident energy. Thus, energy densities on the skin of 6 to 20J/cm² are achieved. The incorporation of the fluorescent material will further extend the output radiation in the desired range, enabling the same exposure of the skin with a lower energy input into flashlamp 14.

Pulsed laser skin treatment shows that energy densities in the range of 0.5 to 10J/cm² with pulse-widths in the range of 0.5msec are generally effective for treating vascular related skin disorders. This range of parameters falls in the range of operation of pulsed non-laser type light sources such as the linear flashlamp. A few steps of neutral density glass filters 18 can also be used to control the energy density on the skin.

For external disorders a typical pulse-width of 5 microsecond is used. A 20J/cm electrical energy density input into a 5mm bore flashlamp results in an energy density on the skin of 10J/cm². Cutting off the hard UV portion of the spectrum results in 90% energy transmission, or skin exposure to an energy density of close to 10 J/cm². This energy density is high enough to evaporate external marks on the skin.

Device 10 can be provided as two units: a lightweight unit held by a physician using handle 13, with

the hand-held unit containing flashlamp 14, filters 18 and iris 20 that together control the spectrum and the size of the exposed area and the detectors that measure the reflectivity and the instantaneous skin temperature. The power supply, the PFN's and the electrical controls are contained in a separate box (not shown) that is connected to the hand-held unit via a flexible cable. This enables ease of operation and easy access to the areas of the skin that need to be treated.

The invention has thus far been described in conjunction with skin treatment. However, using a flashlamp rather than a laser in invasive treatments provides advantages as well. Procedures such as lithotripsy or removal of blood vessel blockage may be performed with a flashlamp. Such a device may be similar to that shown in Figures 1 and 2, and may use the electronics of Figure 3 to produce the flash. However, to properly couple the light to an optical fibre a number of couplers 40, 80 and 90 are shown in Figures 4 and 8-10, respectively.

Coupler 40 includes an optical source of high intensity incoherent and isotropic pulsed light such as a linear flash tube 42, a light reflector 44 which delivers the light energy to an optical fibre 46. The latter has a generally conical edge in the embodiment of Figure 4. Optical fibre 46 transfers the light from light collection system 44 to the treatment area. In general, coupler 40 couples pulsed light from a flash tube into an optical fibre and has applications in medical, industrial and domestic areas.

For example, coupler 40 may be used in material processing to rapidly heat or ablate a portion of a material being processed, or to induce a photo-chemical process. Alternatively, coupler 40 may be used in a photography application to provide a flash for picture taking. Using such a coupler would allow the flash bulb to be located inside the camera, with the light transmitted to outside the camera using an optical fibre. As one skilled in the art should recognise coupler 40 allows the use of incoherent light in many applications that coherent or incoherent light has been used in the past.

To provide for coupling the light to an optical fibre, flash tube 42 has a toroidal shape, shown in Figures 5 and 6, and is disposed inside reflector 44. In addition to the toroidal shape other shapes, such as a continuous helix, may be used for flash tube 42. However, a helical tube is more difficult to manufacture than a toroidal tube. Referring now to Figure 6, flash tube 42 is generally in the shape of a torus, but is not a perfect torus since the electrodes located at the end of the torus have to be connected to the power source. This does not create a significant disturbance in the circular shape of flash tube 42, since the connection to the electrodes can be made quite small.

Reflector 44 collects and concentrates the light, and has a cross-section of substantially an ellipse, in

a plane perpendicular to the minor axis of the toroidal flash tube 42. The major axis of this ellipse preferably forms a small angle with the major axis of toroidal lamp 42. The exact value of the angle between the ellipse axis and the main axis of lamp 42 depends on the Numerical Aperture (NA) of the optical fibre.

The toroidal flash tube is positioned so that its minor axis coincides with the focus of the ellipse. The other focus of the ellipse is at the edge of optical fibre 46. Reflector 44 may be machined from metal with the inner surfaces polished for good reflectivity. Aluminum is a very good reflector with high reflectivity in the visible and ultraviolet, and it may be used for this purpose. The reflector can be machined in one piece and then cut along a surface perpendicular to the main axis of the device. This will enable integration of the toroidal flash tube into the device.

As shown in Figure 4, the edge of optical fibre 46 is a cone with a small opening angle, so that the total area of the fibre exposed to the light from the flash tube is increased. Referring now to Figure 7 the geometry for coupling light into a conical tip is shown. It is assumed here that the light comes from a region in space with a refractive index of n_2 and that the conical section of the fibre (as well as the rest of the fibre core) has a refractive index of n_1 .

Not all the light rays hitting the cone are trapped in it. For light rays that propagate in a plane that contains the major axis of the system, a condition can be derived for the angle of a ray that will be trapped and absorbed in the fibre. This condition is shown in Equation 3.

$$\sin(\mu_{\text{crit}}) = \cos(\beta) - (n_1^2/n_2^2 - 1) \sin(\beta) \quad (\text{Eq. 3})$$

Light will be trapped in the conical portion of the optical fibre if the incidence angle μ is larger than μ_{crit} calculated from Equation 3. Trapping is possible only if $n_1 > n_2$. If the medium outside of the fibre is air, $n_2 = 1$. Not all of the light trapped in the conical section of the fibre will also be trapped in the straight portion of the fibre if a fibre with a core and a cladding is used. If a fibre with a core and no cladding is used (air cladding), then all the rays captured in the conical section of the fibre will also be trapped in the straight section of the fibre.

The configuration shown in Figure 4 can also be used with a fluid filling the volume between the reflector and the optical fibre. A very convenient fluid for this purpose may be water. Water is also very effective in cooling the flashlamp if high repetition rate pulses are used. The presence of a fluid reduces the losses that are associated with glass to air transitions, such as the transition between the flashlamp envelope material and air. If a fluid is used in the reflector volume, then its refractive index can be chosen such that all the rays trapped in the conical section are also trapped in the fibre, even if core/cladding fibres are used.

Another way of configuring the fibre in the reflector is by using a fibre with a flat edge. This configuration is shown in Figure 8 and has trapping efficiency very close to the trapping efficiency of the conical edge. Many other shapes of the fibre edge, such as spherical shapes, can also be used. The configuration of the fibre edge also has an effect on the distribution of the light on the exit side of the fibre and it can be chosen in accordance with the specific application of the device.

The device may be used with a variety of optical fibres. Single, or a small number of millimetre or sub-millimetre diameter fibres, will typically be used in invasive medical applications. In other applications, particularly in industrial and domestic applications, it may be preferable to use a fibre having a larger diameter, or a larger bundle of fibres, or a light guide.

Figures 9 and 10 show a coupler 90 for coupling a linear flash tube 92 through a linear to circular fibre transfer unit 94 to a fibre bundle 96. A reflector 98 has an elliptical cross-section, shown in Figure 10, in a plane parallel to the axis of linear flash tube 92 in this embodiment. Tube 92 is located on one focus of the ellipse while the linear side of linear to circular bundle converter 94 is located at the other focus of the ellipse. This configuration is relatively simple to manufacture and commercially available linear to circular converters such as 25-004-4 available from General Fibre Optics may be used. This configuration is particularly useful for larger exposure areas of the fibre, or for flash illumination purposes.

The energy and power densities that can be achieved by this invention are high enough to get the desired effects in surface treatment or medical applications. For the embodiment shown in Figure 4 the total energy and power densities can be estimated as follows. For a typical toroidal lamp with a 4mm bore diameter and a major diameter of 3.3cm an electrical linear energy density input of 10J/cm into the lamp can be used with a 5µsec pulse width. The light output of the lamp will be 5 to 6J/cm for optimal electrical operating conditions. For the reflector shown in Figure 4, 50% of the light generated in the lamp will reach the lower focus. Thus, a total energy flux on the focus of 25 to 30J may be obtained. For embodiments shown in Figure 4 or Figure 8 the total cross-section area of reflector at the focal plane has a cross-section of 0.8cm².

Energy densities on the order of 30 to 40J/cm² at the entrance to the fibre should be attained with this cross-section. This corresponds to power densities of 5 to 10MW/cm², which are the typical power densities used in medical or material processing applications.

For longer pulses, higher linear electrical energy densities into the lamp can be used. For a 1msec pulse to the flash tube a linear electrical energy density of 100J/cm can be used. The corresponding energy density at the focal area would be up to

300J/cm². Such energy densities are very effective in industrial cleaning and processing applications as well as in medical applications.

Alternative embodiments for coupling the optical fibre to an extended light source such as a linear flashlamp are shown in Figures 11 and 12. In the embodiment of Figure 11 an optical fibre 101 is wound around a lamp 102 and a lamp envelope 103. Some of the light that is produced by the light source is coupled into the fibre. If the light rays are propagating in the direction that is trapped by the fibre then this light will propagate in the fibre and it can be used at a fibre output 104. One limitation of this configuration is the fact that most of the light emitted by lamp 103 travels in a direction perpendicular to the surface of lamp 103 and cannot be trapped in fibre 101.

The embodiment shown in Figure 12 overcomes this problem. A doped optical fibre 105 is wound around lamp 102 and envelope 103, rather than an undoped fibre such as fibre 101 of Figure 11. The dopant is a fluorescent material which is excited by the radiation emanating from lamp 102 and radiates light inside the fibre. This light is radiated omnidirectionally and the part of it that is within the critical angle of fibre 105 is trapped and propagates through the fibre and can be used at fibre output 104. The angle of light that is trapped in the fibre is the critical angle of the material from which the optical fibre or optical wave guide is made. For a fibre (or optical wave guide) in air this angle is given by $\sin \alpha = 1/n$.

Typically for glass or other transparent materials $n = 1.5$ and $\alpha = 41.8^\circ$. This corresponds to a trapping efficiency of more than 10% of the light emitted by fluorescence inside the fibre. If we assume a 50% efficiency of the fluorescence process we find out that more than 5% of the light produced by the lamp is trapped and propagated down the fibre. For example, a 4" (10.2cm) lamp with a linear electrical energy input of 300J/inch (118 J/cm) and 50% electrical to light conversion efficiency would couple 2.5% of its electrical energy into the fibre. This corresponds, for the 4" (10.2cm) lamp case to a total light energy of 30J of light. This embodiment has the additional advantage of transferring the wavelength emitted by the lamp to a wavelength that may be more useful in some of the therapeutic or processing applications mentioned before. Thus, fluorescent material doped in the fibre can be chosen in accordance with an emission wavelength determined by the specific application of the device.

Thus, it should be apparent that there has been provided in accordance with the present invention a flashlamp and coupler that fully satisfy the objectives and advantages set forth above. Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to

embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

Claims

1. A therapeutic treatment device characterised in that an incoherent light source (14) is operable to provide a pulsed light output for treatment.
2. A treatment device as claimed in claim 1 further characterised in that a variable pulse width pulse forming circuit is electrically connected to said light source.
3. A treatment device as claimed in any one of the preceding claims, further characterised in that said light source is a flashlamp (14).
4. A treatment device as claimed in any one of the preceding claims, further characterised in that said light source comprises means for providing pulses having a width in the range of between substantially 0.5 and 10 microsec and an energy density of the light on the skin of up to about 10J/cm², whereby the light treats external disorders of the skin, such as: tattoos, pigmented lesions or birth and age marks.
5. A treatment device as claimed in any one of the preceding claims, further characterised in that said light source (14) is mounted in a housing (12) suitable for being disposed adjacent a skin treatment area, said housing having a reflector (16) mounted therein proximate said light source, and said housing having an opening, with an iris (20) mounted about said opening, and at least one optical filter (18) mounted proximate said opening.
6. A treatment device as claimed in claim 5, further characterised in that a means (18) for providing controlled energy density, filtered, pulsed light output through said opening and said iris to a skin area for treatment is provided.
7. A treatment device as claimed in claim 5 or 6, further characterised in that a power supply is connected to and external of said housing, wherein said housing includes a handle (13).
8. A device as claimed in any one of the preceding claims, further characterised in that a plurality of optical fibres (96), each having an end disposed within a reflector (98) and a linear to circular fibre transfer unit (94) is disposed to receive light from the light source (92) and provide light to the opt-

ical fibres.

9. A device as claimed in claim 8, wherein a reflector (98) has an elliptical cross-section in a plane parallel to the axis of a light source which comprises a linear flash tube (92), and wherein the linear flash tube is located at one focus of the ellipse while the linear to circular transfer unit (94) is located at the other focus of the ellipse. 5 10
10. A system for providing pulsed light characterised in that:
a pulsed toroidal flash tube incoherent light source (42, 92) has a reflector (44) disposed thereabout, said reflector having a cross-section of substantially an ellipse, in a plane perpendicular to the minor axis of the toroidal flash tube; and at least one optical fibre (46) having an end disposed within said reflector. 15 20
11. A system as claimed in claim 10, further characterised in that the end of the optical fibre has a cone shape. 25
12. A system as claimed in claim 10, further characterised in that the end of the optical fibre is flat.
13. A system as claimed in any one of claims 10 to 12, further characterised in that the optical fibre is air clad. 30

35

40

45

50

55

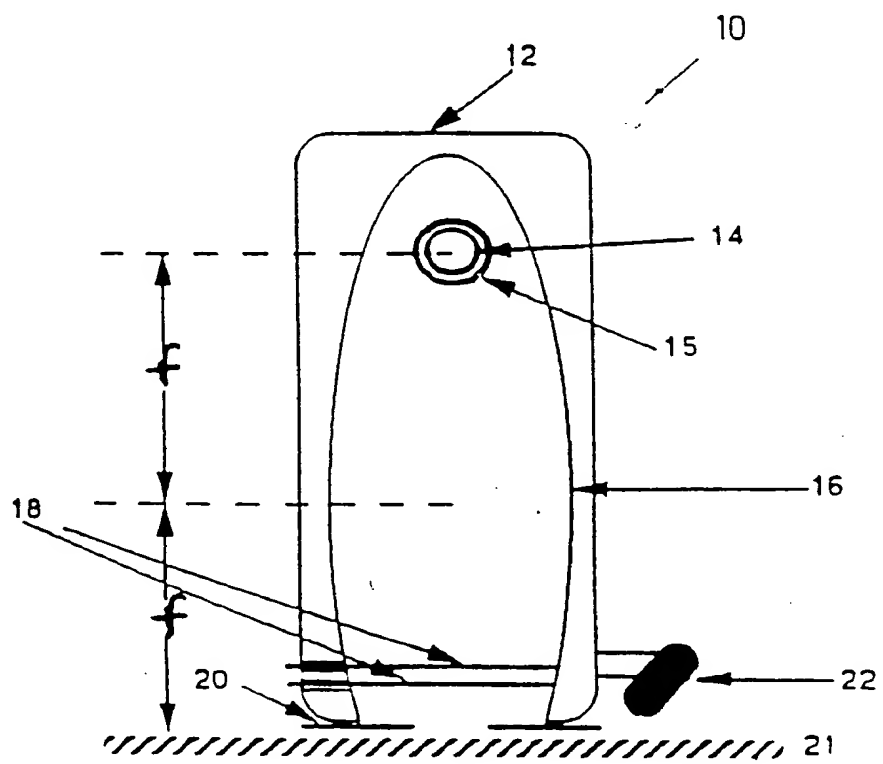


Figure 1

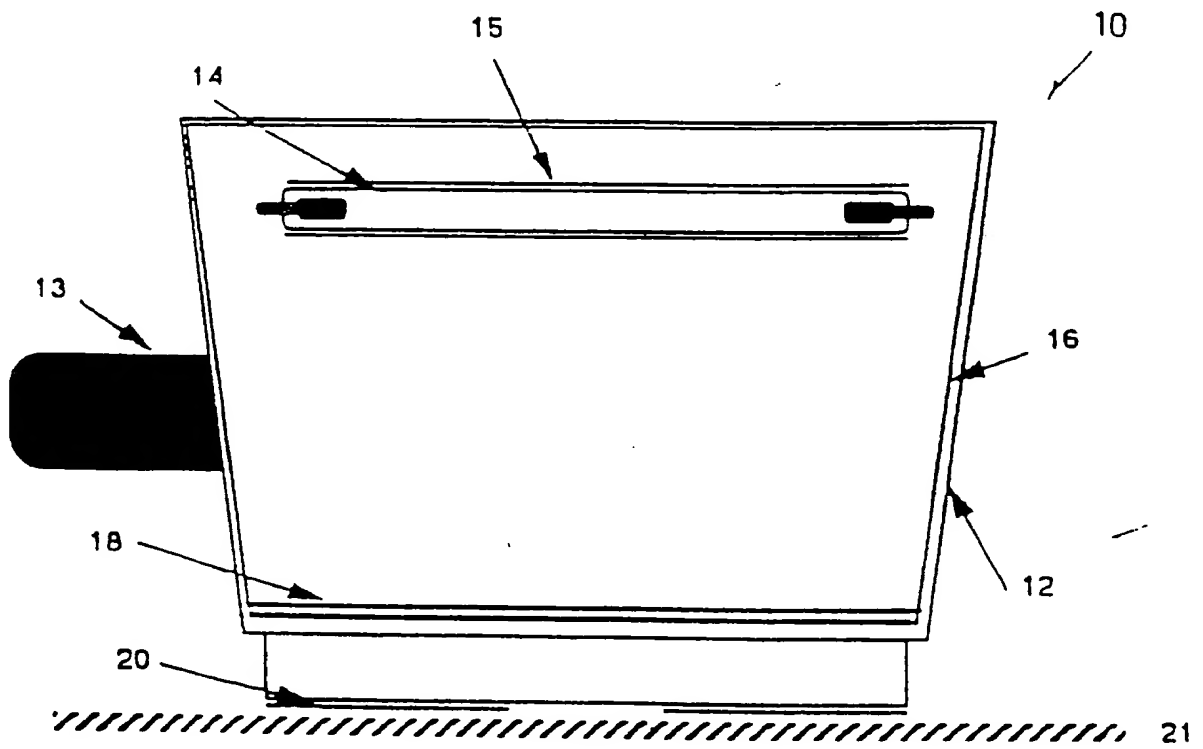


Figure 2

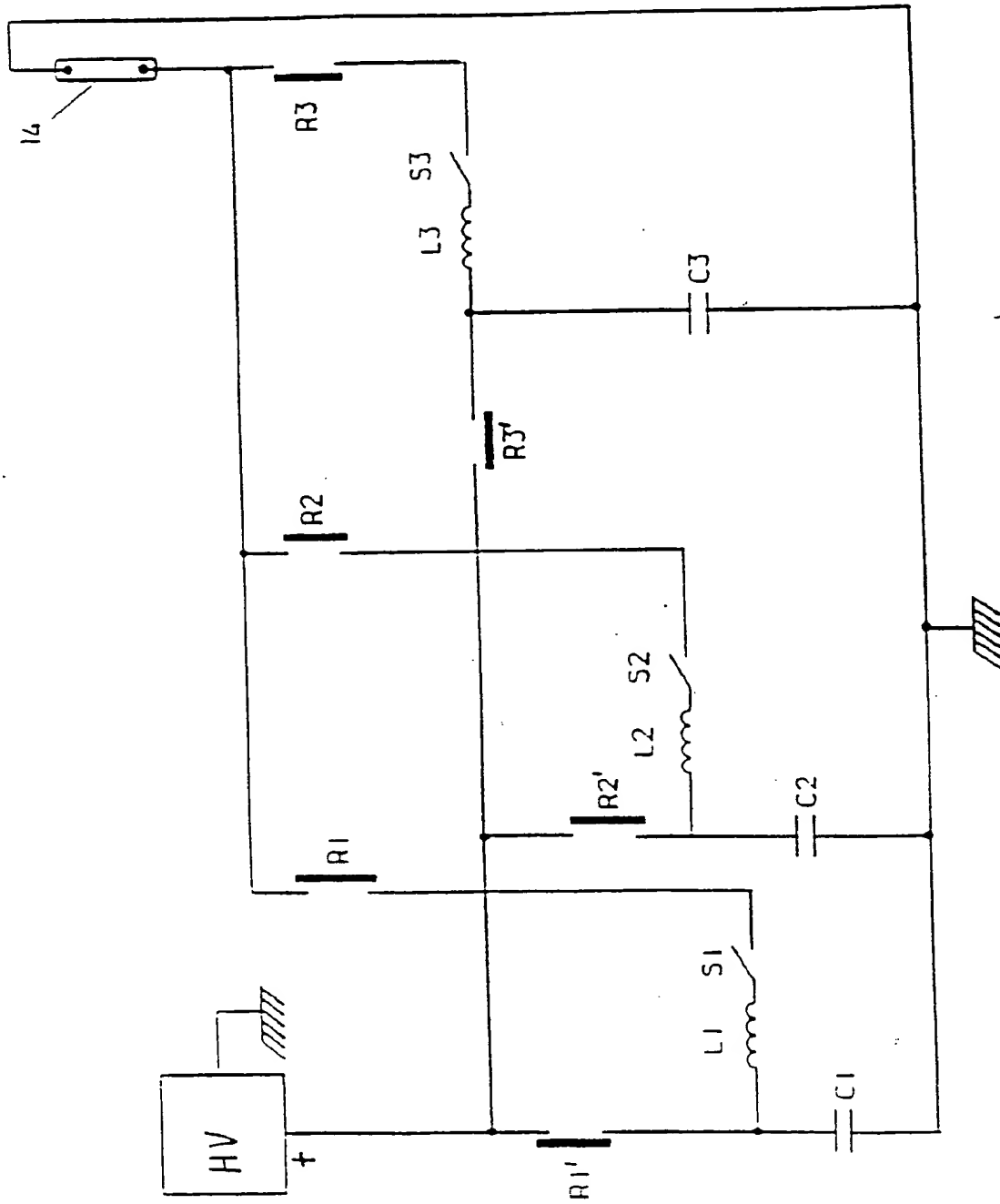


Figure 3

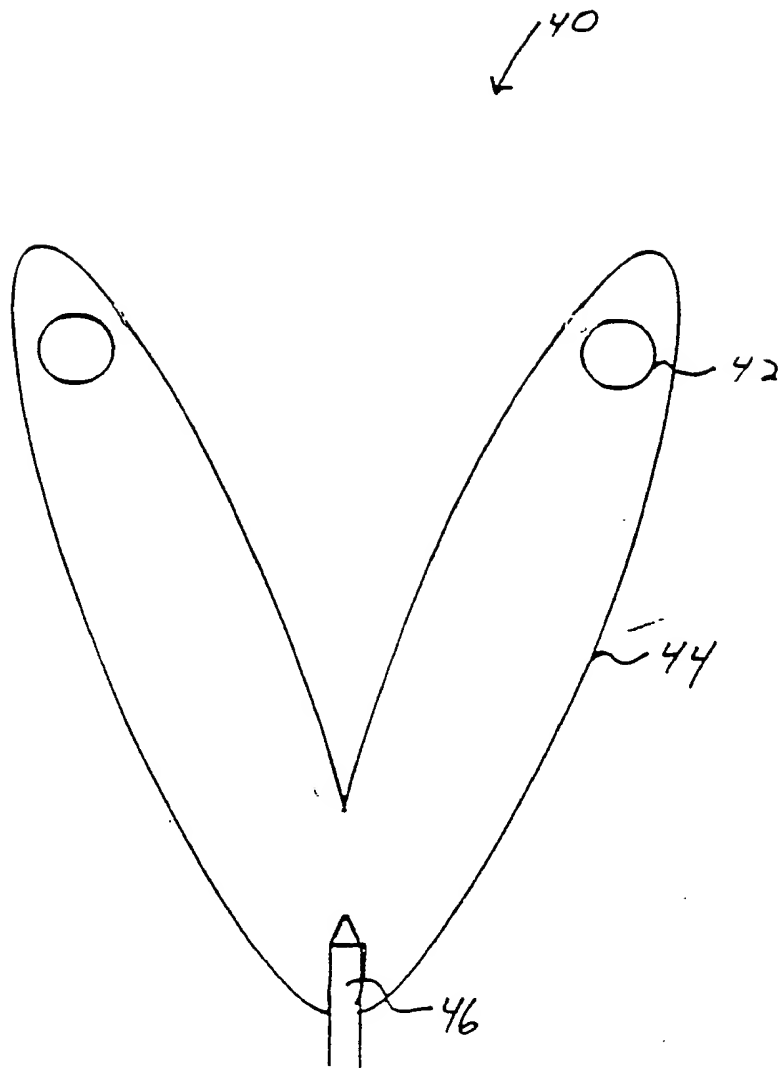


Figure 4

Figure 5

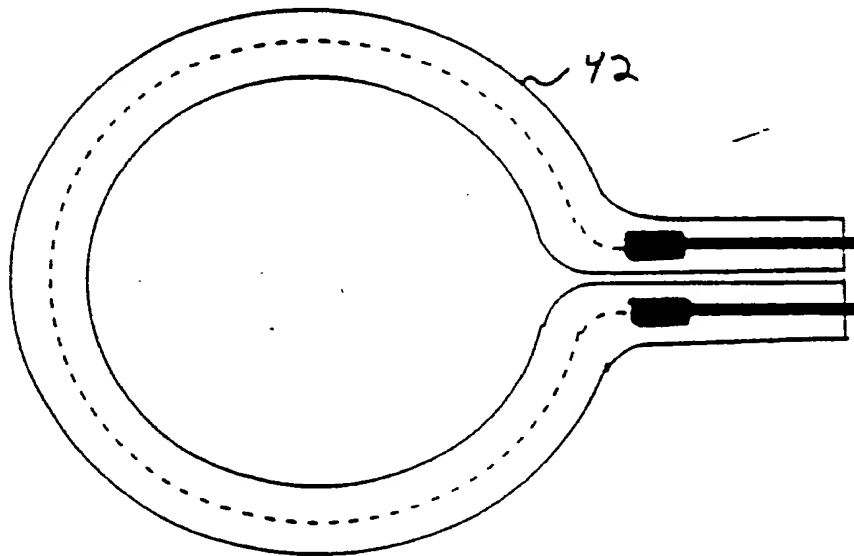
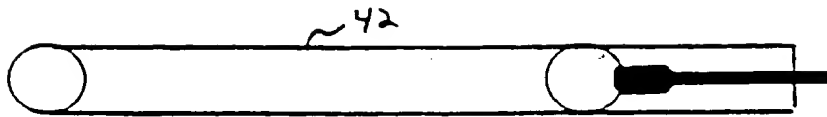


Figure 6

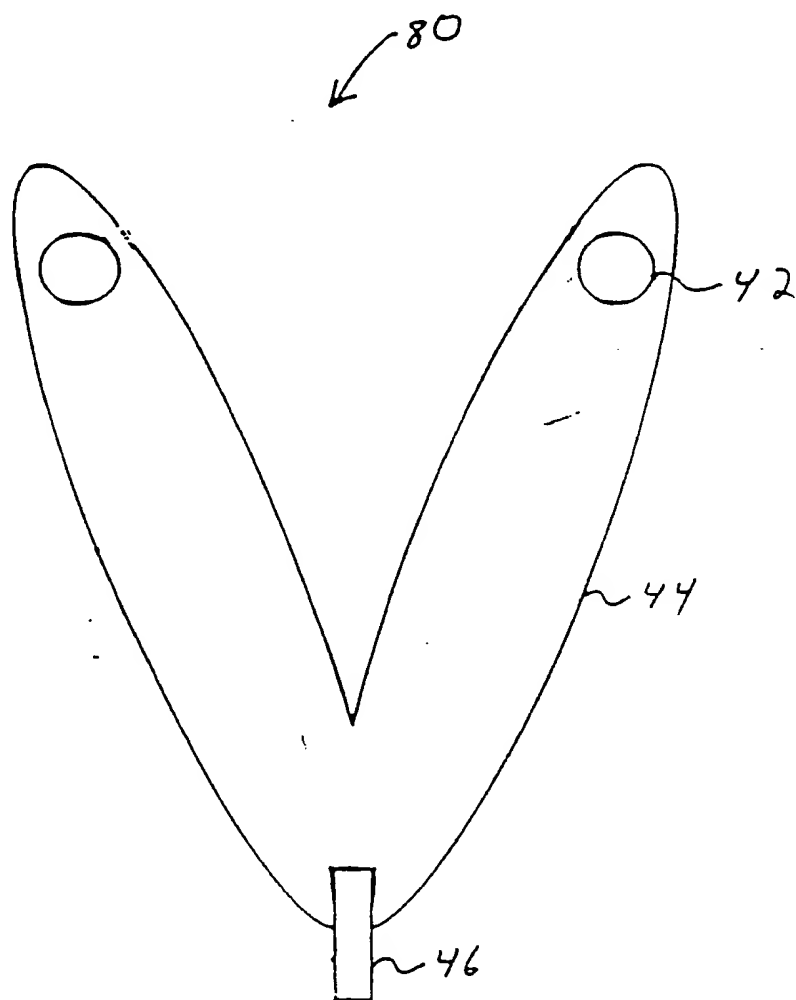


Figure 8

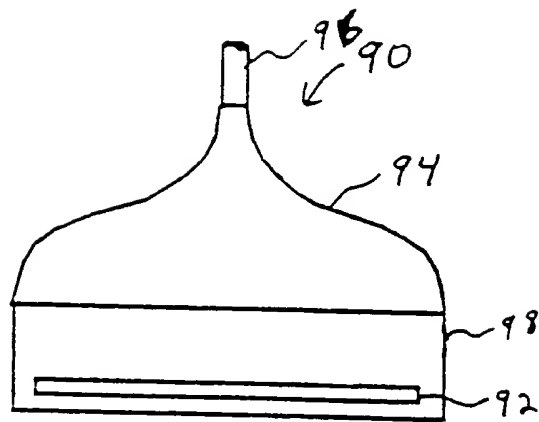


Figure 9

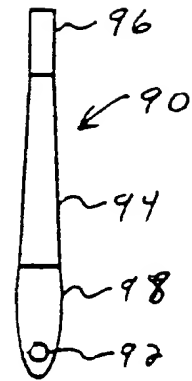


Figure 10

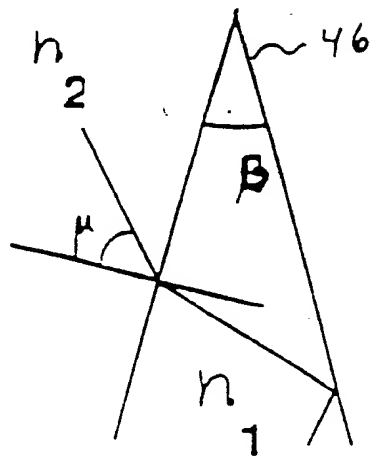


Figure 7

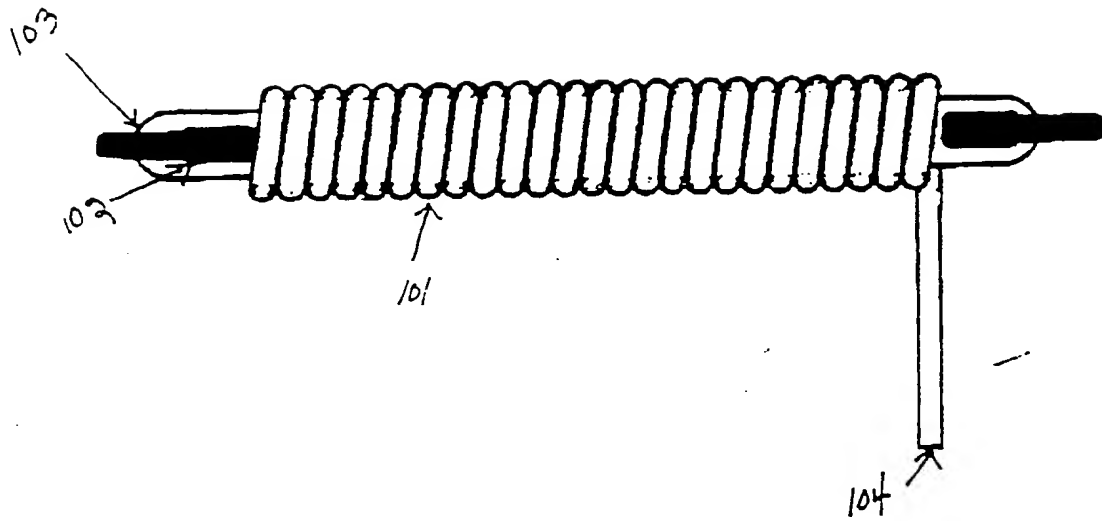


Figure 11

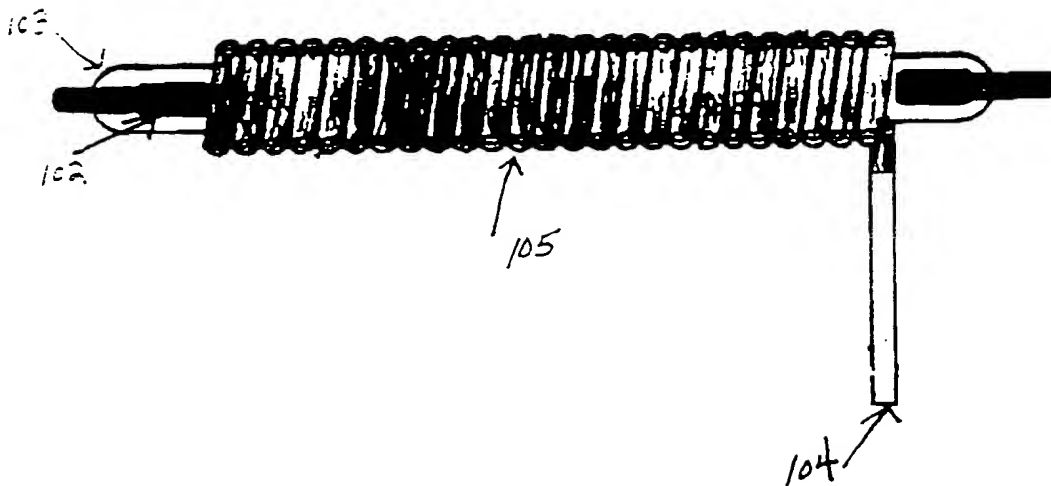


Figure 12



(11) Publication number : **0 565 331 A2**

(12)

EUROPEAN PATENT APPLICATION

(21) Application number : **93302662.7**

(51) Int. Cl.⁵ : **A61N 5/06**

(22) Date of filing : **05.04.93**

(30) Priority : **09.04.92 IL 101547**
20.10.92 US 964210

(43) Date of publication of application :
13.10.93 Bulletin 93/41

(84) Designated Contracting States :
AT BE CH DE DK ES FR GB GR IE IT LI LU MC
NL PT SE

(71) Applicant : **ESC Inc**
329 Central Street
Newton, Massachusetts, 02166 (US)

(72) Inventor : **Eckhouse, Shimon**
27 Ester-Rabin Street
Haifa 34987 (IL)

(74) Representative : **Cookson, Barbara Elizabeth**
et al
Titmuss Salner & Webb, 2 Serjeants' Inn
London EC4Y 1LT (GB)

(54) **Therapeutic electromagnetic treatment.**

(57) A therapeutic treatment device is disclosed and includes a housing (12) and an incoherent light source (14) such as a flashlamp disposed in the housing. The flashlamp provides a pulsed light output for treatment of external skin disorders. To provide light to the treatment area the housing has an opening that is disposed adjacent a skin treatment area. A reflector (16) is mounted within the housing near the light source to reflect the light to the treatment area. At least one optical filter (18) and an iris (20) are mounted near the opening in the housing. Power to the lamp is provided by a pulse forming circuit that can provide a variable pulse width.

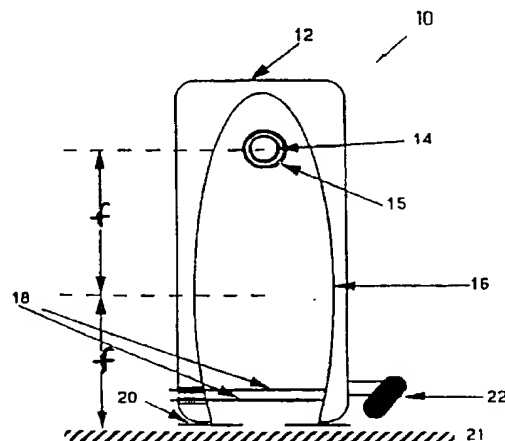


Figure 1

EP 0 565 331 A2

The present invention relates generally to the art of therapeutic electromagnetic treatment and more specifically to a method and apparatus for utilising a spatially extended pulsed light source such as a flashlamp (flash tube) for such a treatment or, efficiently focusing light from the flashlamp into optical fibres for therapeutic treatment or other applications.

It is known in the prior art to use electromagnetic radiation in medical application for therapeutic uses such as treatment of skin disorders. For example, US-A-4,298,005 (Mutzhas) describes a continuous ultraviolet lamp with cosmetic, photobiological, and photochemical applications. A treatment based on using the UV portion of the spectrum and its photochemical interaction with the skin is described. The power delivered to the skin using Mutzhas' lamp is described as 150W/m², which does not have a significant effect on skin temperature.

In addition to prior art treatment involving UV light, lasers have been used for dermatological procedures, including Argon lasers, CO₂ lasers, Nd(Yag) lasers, Copper vapor lasers, ruby lasers and dye lasers. For example, US-A-4,829,262 (Furumoto), describes a method of constructing a dye laser used in dermatology applications. Two skin conditions which may be treated by laser radiation are external skin irregularities such as local differences in the pigmentation or structure of the skin, and vascular disorders lying deeper under the skin which cause a variety of skin abnormalities including port wine stains, telangiectasias, leg veins and cherry and spider angiomas. Laser treatment of these skin disorders generally includes localised heating of the treatment area by absorption of laser radiation. Heating the skin changes or corrects the skin disorder and causes the full or partial disappearance of the skin abnormality.

Certain external disorders such as pigmented lesions can also be treated by heating the skin very fast to a high enough temperature to evaporate parts of the skin. Deeper-lying vascular disorders are more typically treated by heating the blood to a high enough temperature to cause it to coagulate. The disorder will then eventually disappear. To control the treatment depth a pulsed radiation source is often used. The depth the heat penetrates in the blood vessel is controlled by controlling the pulse width of the radiation source. The absorption and scattering coefficients of the skin also affect the heat penetration. These coefficients are a function of the constituents of skin and the wavelength of the radiation. Specifically, the absorption coefficient of light in the epidermis and dermis tends to be a slowly varying, monotonically decreasing function of wavelength. Thus, the wavelength of the light should be chosen so that the absorption coefficient is optimised for the particular skin condition and vessel size being treated.

The effectiveness of lasers for applications such as tattoo removal and removal of birth and age marks

is diminished because lasers are monochromatic. A laser of a given wavelength may be effectively used to treat a first type of skin pigmentation disorder, but, if the specific wavelength of the laser is not absorbed efficiently by skin having a second type of disorder, it will be ineffective for the second type of skin disorder. Also, lasers are usually complicated, expensive to manufacture, large for the amount of power delivered, unreliable and difficult to maintain.

The wavelength of the light also affects vascular disorder treatment because blood content in the vicinity of the vascular disorders varies, and blood content affects the absorption coefficient of the treatment area. Oxyhemoglobin is the main chromophore which controls the optical properties of blood and has strong absorption bands in the visible region. More particularly, the strongest absorption peak of oxyhemoglobin occurs at 418nm and has a band-width of 60nm. Two additional absorption peaks with lower absorption coefficients occur at 542 and 577nm. The total band-width of these two peaks is on the order of 100nm. Additionally, light in the wavelength range of 500 to 600nm is desirable for the treatment of blood vessel disorders of the skin since it is absorbed by the blood and penetrates through the skin. Longer wavelengths up to 1000nm are also effective since they can penetrate deeper into the skin, heat the surrounding tissue and, if the pulse-width is long enough, contribute to heating the blood vessel by thermal conductivity. Also, longer wavelengths are effective for treatment of larger diameter vessels because the lower absorption coefficient is compensated for by the longer path of light in the vessel.

In addition to being used for treating skin disorders, lasers have been used for invasive medical procedures such as lithotripsy and removal of blood vessel blockage. In such invasive procedures laser light is coupled to optical fibres and delivered through the fibre to the treatment area. In lithotripsy the fibre delivers light from a pulsed laser to a kidney or gallstone and the light interaction with the stone creates a shock wave which pulverises the stone. To remove blood vessel blockage the light is coupled to the blockage by the fibre and disintegrates the blockage. In either case the shortcomings of lasers discussed above with respect to laser skin treatment are present. Accordingly, a treatment device for lithotripsy and blockage removal utilising a flashlamp would be desirable.

To effectively treat an area the light from the source must be focused on the treatment area. Coupling pulsed laser light into optical fibres in medicine is quite common. The prior art describes coupling isotropic incoherent point sources such as CW lamps into small optical fibres. For example, US-A-4,757,431 (Cross, et al.) discloses a method for focusing incoherent point sources with small filaments or an arc lamp with an electrode separation of 2mm

into a small area. Point (or small) sources are relatively easy to focus without large losses in energy because of the small size of the source. Also, US-A-4,022,534 (Kishner) discloses light produced by a flash tube and the collection of only a small portion of the light emitted by the tube into an optical fibre.

However, the large dimension of an extended source such as a flashlamp make it difficult to focus large fractions of its energy into small areas. Coupling into optical fibres is even more difficult since not only must a high energy density be achieved, but the angular distribution of the light has to be such that trapping in the optical fibre can be accomplished. Thus, it is desirable to have a system for coupling the output of a high intensity, extended, pulsed light source into an optical fibre.

In order to solve the technical problems outlined above including the specificity of prior art systems and their technical complexity and expense, the device or system of the present invention is characterised by the provision of pulsed incoherent radiation.

Accordingly, in one embodiment, a wide band electromagnetic radiation source that covers the near UV and the visible portion of the spectrum would be desirable for treatment of external skin and vascular disorders. The overall range of wavelengths of the light source should be sufficient to optimise treatment for any of a number of applications. Such a therapeutic electromagnetic radiation device should also be capable of providing an optimal wavelength range within the overall range for the specific disorder being treated. The intensity of the light should be sufficient to cause the required thermal effect by raising the temperature of the treatment area to the required temperature. Also, the pulse-width should be variable over a wide enough range so as to achieve the optimal penetration depth for each application. Therefore, it is desirable to provide a light source having a wide range of wavelengths, which can be selected according to the required skin treatment, with a controlled pulse-width and a high enough energy density for application to the affected area.

Pulsed non-laser type light sources such as linear flashlamps provide these benefits. The intensity of the emitted light can be made high enough to achieve the required thermal effects. The pulse-width can be varied over a wide range so that control of thermal depth penetration can be accomplished. The typical spectrum covers the visible and ultraviolet range and the optical bands most effective for specific applications can be selected, or enhanced using fluorescent materials. Moreover, non-laser type light sources such as flashlamps are much simpler and easier to manufacture than lasers, are significantly less expensive for the same output power and have the potential of being more efficient and more reliable. They have a wide spectral range that can be optimised for a variety of specific skin treatment applications. These

sources also have a pulse length that can be varied over a wide range which is critical for the different types of skin treatments.

The scope of the invention is defined in the claims and the embodiments outlined below are specific combinations suitable for implementing the invention.

According to a first embodiment of the invention a therapeutic treatment device comprises a housing and an incoherent light source, suitably a flashlamp, operable to provide a pulsed light output for treatment, disposed in the housing. The housing has an opening and is suitable for being disposed adjacent a skin treatment area. A reflector is mounted within the housing proximate the light source, and at least one optical filter is mounted proximate the opening in the housing. An iris is mounted coextensively with the opening. Power to the lamp is provided by a variable pulse width pulse forming circuit. Thus, the treatment device provides controlled density, filtered, pulsed light output through an opening in the housing to a skin area for treatment.

According to a second embodiment of the invention a method of treatment with light energy comprises the steps of providing a high power, pulsed light output from a non-laser, incoherent light source and directing the pulsed light output to a treatment area. The pulse width of the light output is controlled and focused so that the power density of the light is controlled. Also, the light is filtered to control the spectrum of the light.

According to a third embodiment of the invention a coupler comprises an incoherent light source such as a toroidal flashlamp. A reflector is disposed around the incoherent light source and at least one optical fibre or light guide. The fibre has an end disposed within the reflector. This end collects the light from the circular lamp. In a similar coupling configuration fibres may be provided, along with a linear to circular fibre transfer unit disposed to receive light from the light source and provide light to the optical fibres. The reflector has an elliptical cross-section in a plane parallel to the axis of the linear flash tube, and the linear flash tube is located at one focus of the ellipse while the linear to circular transfer unit is located at the other focus of the ellipse.

For a better understanding of the invention, reference is made to the accompanying diagrammatic drawings, in which:

Figure 1 is a cross-sectional view of an incoherent, pulsed light source skin treatment device;

Figure 2 is a side view of the light source of Figure 1;

Figure 3 is a schematic diagram of a pulse forming network with a variable pulse width for use with the skin treatment device of Figures 1 and 2;

Figure 4 is a cross-sectional view of a coupler for coupling light from a toroidal flash tube into an

optical fibre with a conical edge;

Figure 5 is a side view of a toroidal flash tube;

Figure 6 is a top view of a toroidal flash tube;

Figure 7 shows the geometry for coupling into a conical section;

Figure 8 is a cross-sectional view of a coupler for coupling light from a toroidal flash tube into an optical fibre with a flat edge;

Figure 9 is a front sectional view of a coupler for coupling light from a linear flash tube into a circular fibre bundle;

Figure 10 is a side sectional view of the coupler of Figure 9;

Figure 11 is a front view of a coupler for coupling light from a linear flash tube into an optical fibre; and

Figure 12 is a front view of a coupler for coupling light from a linear flash tube into a doped optical fibre.

In the various figures, like reference numerals are used to describe like components.

Before explaining at least one embodiment of the invention in detail it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practised or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

Referring now to Figures 1 and 2, cross-sectional and side views of an incoherent, pulsed light source skin treatment device 10 constructed and operated in accordance with the principles of the present invention are shown. The device 10 may be seen to include a housing 12, having an opening therein, a handle 13 (Figure 2 only), a light source 14 having an outer glass tube 15, an elliptical reflector 16, a set of optical filters 18, an iris 20 and a detector 22 (Figure 1 only). Light source 14, which is mounted in housing 12, may be a typical incoherent light source such as a gas filled linear flashlamp Model No. L5568 available from ILC. The spectrum of light emitted by gas filled linear flashlamp 14 depends on current density, type of glass envelope material and gas mixture used in the tube. For large current densities (e.g., 3000 A/cm² or more) the spectrum is similar to a black body radiation spectrum. Typically, most of the energy is emitted in the 300 to 1000nm wavelength range.

To treat a skin (or visible) disorder a required light density on the skin must be delivered. This light density can be achieved with the focusing arrangement shown in Figures 1 and 2. Figure 1 shows a cross-section view of reflector 16, also mounted in housing 12. As shown in Figure 1, the cross-section of reflector 16 in a plane is perpendicular to the axis of flashlamp 14 is an ellipse. Linear flashlamp 14 is located

at one focus of the ellipse and reflector 16 is positioned in such a way that the treatment area of skin 21 is located at the other focus. The arrangement shown is similar to focusing arrangements used with lasers and efficiently couples light from flashlamp 14 to the skin. This arrangement should not, however, be considered limiting. Elliptical reflector 16 may be a metallic reflector, typically polished aluminum which is an easily machinable reflector and has a very high reflectivity in the visible, and the UV range of the spectrum can be used. Other bare or coated metals can also be used for this purpose.

Optical and neutral density filters 18 are mounted in housing 12 near the treatment area and may be moved into the beam or out of the beam to control the spectrum and intensity of the light. Typically, 50 to 100nm band-width filters, as well as low cut-off filters in the visible and ultraviolet portions of the spectrum, are used. In some procedures it is desirable to use most of the spectrum, with only the UV portion being cut off. In other applications, mainly for deeper penetration, it is preferable to use narrower band-widths. The band-width filters and the cut-off filters are readily available commercially.

Glass tube 15 is located coaxially with flashlamp 14 and has fluorescent material deposited on it. Glass tube 15 will typically be used for treatment of coagulation of blood vessels to optimise the energy efficiency of device 10. The fluorescent material can be chosen to absorb the UV portion of the spectrum of flashlamp 14 and generate light in the 500 to 650nm range that is optimised for absorption in the blood. Similar materials are coated on the inner walls of commercial fluorescent lamps. A typical material used to generate "warm" white light in fluorescent lamps has a conversion efficiency of 80%, has a peak emission wavelength of 570nm and has a bandwidth of 70nm and is useful for absorption in blood. The few millisecond decay time of these phosphors is consistent with long pulses that are required for the treatment of blood vessels.

Other shapes or configurations of flashlamp 14 such as circular, helical, short arc and multiple linear flashlamps may be used. Reflector 16 may have other designs such as parabolic or circular reflectors. The light source can also be used without a reflector and the required energy and power density may be achieved by locating light source 14 in close proximity to the treatment area.

Iris 20 is mounted in housing 12 between optical filters 18 and the treatment area and controls the length and the width of the exposed area, i.e. by collimating the output of flashlamp 14. The length of flashlamp 14 controls the maximum length that can be exposed. Typically a 8cm long (arc length) tube will be used and only the central 5cm of the tube is exposed. Using the central 5cm assures a high degree of uniformity of energy density in the exposed skin

area. Thus, in this embodiment the iris 20 (also called a collimator) will enable exposure of skin areas of a maximum length of 5cm. The iris 20 may be closed to provide a minimum exposure length of one millimetre. Similarly, the width of the exposed skin area can be controlled in the range of 1 to 5mm for a 5mm wide flashlamp. Larger exposed areas can be easily achieved by using longer flash tubes or multiple tubes, and smaller exposure areas are obtainable with an iris that more completely collimates the beam. The present invention provides a larger exposure area compared to prior art lasers or point sources and is very effective in the coagulation of blood vessels since blood flow interruption over a longer section of the vessel is more effective in coagulating it. The larger area exposed simultaneously also reduces the required procedure time.

Detector 22 (Figure 1) is mounted outside housing 12 and monitors the light reflected from the skin. Detector 22 combined with optical filters 18 and neutral density filters can be used to achieve a quick estimate of the spectral reflection and absorption coefficients of the skin. This may be carried out at a low energy density level prior to the application of the main treatment pulse. Measurement of the optical properties of the skin prior to the application of the main pulse is useful to determine optimal treatment conditions. As stated above, the wide spectrum of the light emitted from the non-laser type source enables investigation of the skin over a wide spectral range and choice of optimal treatment wavelengths.

In an alternative embodiment, detector 22 or a second detector system may be used for real-time temperature measurement of the skin during its exposure to the pulsed light source. This is useful for skin thermolysis applications with long pulses in which light is absorbed in the epidermis and dermis. When the external portion of the epidermis reaches too high a temperature, permanent scarring of the skin may result. Thus, the temperature of the skin should be measured. This can be realised using infra-red emission of the heated skin, to prevent over-exposure.

A typical real-time detector system would measure the infra-red emission of the skin at two specific wavelengths by using two detectors and filters. The ratio between the signals of the two detectors can be used to estimate the instantaneous skin temperature. The operation of the pulsed light source can be stopped if a preselected skin temperature is reached. This measurement is relatively easy since the temperature threshold for pulsed heating that may cause skin scarring is on the order of 50°C or more, which is easily measurable using infrared emission.

The depth of heat penetration depends on the light absorption and scattering in the different layers of the skin and the thermal properties of the skin. Another important parameter is pulse-width. For a

pulsed light source, the energy of which is absorbed in an infinitesimally thin layer, the depth of heat penetration (d) by thermal conductivity during the pulse can be written as shown in Equation 1:

$$(Eq. 1) \quad d = 4 [k\Delta t/C\rho]^{1/2}$$

where

k = heat conductivity of the material being illuminated;

Δt = the pulse-width of the light pulse;

C = the heat capacity of the material;

ρ = density of the material.

It is clear from Equation 1 that the depth of heat penetration can be controlled by the pulse-width of the light source.

Thus, a variation of pulse-width in the range of 10^{-5} sec to 10^{-1} sec will result in a variation in the thermal penetration by a factor of 100.

Accordingly, the flashlamp 14 provides a pulse width of from 10^{-5} sec to 10^{-1} sec. For treatment of vascular disorders in which coagulation of blood vessels in the skin is the objective the pulse length is chosen to uniformly heat as much of the entire thickness of the vessel as possible to achieve efficient coagulation. Typical blood vessels that need to be treated in the skin have thicknesses in the range of 0.5mm. Thus, the optimal pulse-width, taking into account the thermal properties of blood, is on the order of 100msec. If shorter pulses are used, heat will still be conducted through the blood to cause coagulation, however, the instantaneous temperature of part of the blood in the vessel and surrounding tissue will be higher than the temperature required for coagulation and may cause unwanted damage.

For treatment of external skin disorders in which evaporation of the skin is the objective, a very short pulse-width is used to provide for very shallow thermal penetration of the skin. For example, a 10^{-5} sec pulse will penetrate (by thermal conductivity) a depth of the order of only 5 microns into the skin. Thus, only a thin layer of skin is heated, and a very high, instantaneous temperature is obtained so that the external mark on the skin is evaporated.

Figure 3 shows a variable pulse-width pulse forming circuit comprised of a plurality of individual pulse forming networks (PFN's) that create the variation in pulse-widths of flashlamp 14. The light pulse full width at half maximum (FWHM) of a flashlamp driven by a single element PFN with capacitance C and inductance L is approximately equal to:

$$(Eq.2) \quad \Delta t \approx 2[LC]^{1/2}$$

Flashlamp 14 may be driven by three different PFN's, as shown in Figure 3. The relay contacts R1', R2' and R3' are used to select among three capacitors C1, C2 and C3 that are charged by the high voltage power supply. Relays R1, R2 and R3 are used to select the PFN that will be connected to flashlamp 14. The high voltage switches S1, S2 and S3 are used to discharge the energy stored in the capacitor of the

PFN into flashlamp 14. In one embodiment L1, L2 and L3 have values of 100mH, 1mH and 5mH, respectively, and C1, C2 and C3 have values of 100mF, 1mF and 10mF, respectively.

In addition to the possibility of firing each PFN separately, which generates the basic variability in pulse-width, additional variation can be achieved by firing PFN's sequentially. If, for example, two PFN's having pulse-width Δt_1 and Δt_2 are fired, so that the second PFN is fired after the first pulse has decayed to half of its amplitude, then an effective light pulse-width of this operation of the system will be given by the relation: $\Delta t \approx \Delta t_1 + \Delta t_2$.

The charging power supply typically has a voltage range of 500V to 5kV. The relays should therefore be high voltage relays that can isolate these voltages reliably. The switches S are capable of carrying the current of flashlamp 14 and to isolate the reverse high voltage generated if the PFNs are sequentially fired. Solid-state switches, vacuum switches or gas switches can be used for this purpose.

A simmer power supply (not shown in Figure 3) may be used to keep the flashlamp in a low current conducting mode. Other configurations can be used to achieve pulse-width variation, such as the use of a single PFN and a crowbar switch, or use of a switch with closing and opening capabilities.

Typically, for operation of flashlamp 14 with an electrical pulse-width of 1 to 10msec, a linear electrical energy density input of 100 to 300J/cm can be used. An energy density of 30 to 100J/cm² can be achieved on the skin for a typical flashlamp bore diameter of 5mm. The use of a 500 to 650nm bandwidth transmits 20% of the incident energy. Thus, energy densities on the skin of 6 to 20J/cm² are achieved. The incorporation of the fluorescent material will further extend the output radiation in the desired range, enabling the same exposure of the skin with a lower energy input into flashlamp 14.

Pulsed laser skin treatment shows that energy densities in the range of 0.5 to 10J/cm² with pulse-widths in the range of 0.5msec are generally effective for treating vascular related skin disorders. This range of parameters falls in the range of operation of pulsed non-laser type light sources such as the linear flashlamp. A few steps of neutral density glass filters 18 can also be used to control the energy density on the skin.

For external disorders a typical pulse-width of 5 microsecond is used. A 20J/cm electrical energy density input into a 5mm bore flashlamp results in an energy density on the skin of 10J/cm². Cutting off the hard UV portion of the spectrum results in 90% energy transmission, or skin exposure to an energy density of close to 10 J/cm². This energy density is high enough to evaporate external marks on the skin.

Device 10 can be provided as two units: a light-weight unit held by a physician using handle 13, with

the hand-held unit containing flashlamp 14, filters 18 and iris 20 that together control the spectrum and the size of the exposed area and the detectors that measure the reflectivity and the instantaneous skin temperature. The power supply, the PFN's and the electrical controls are contained in a separate box (not shown) that is connected to the hand-held unit via a flexible cable. This enables ease of operation and easy access to the areas of the skin that need to be treated.

The invention has thus far been described in conjunction with skin treatment. However, using a flashlamp rather than a laser in invasive treatments provides advantages as well. Procedures such as lithotripsy or removal of blood vessel blockage may be performed with a flashlamp. Such a device may be similar to that shown in Figures 1 and 2, and may use the electronics of Figure 3 to produce the flash. However, to properly couple the light to an optical fibre a number of couplers 40, 80 and 90 are shown in Figures 4 and 8-10, respectively.

Coupler 40 includes an optical source of high intensity incoherent and isotropic pulsed light such as a linear flash tube 42, a light reflector 44 which delivers the light energy to an optical fibre 46. The latter has a generally conical edge in the embodiment of Figure 4. Optical fibre 46 transfers the light from light collection system 44 to the treatment area. In general, coupler 40 couples pulsed light from a flash tube into an optical fibre and has applications in medical, industrial and domestic areas.

For example, coupler 40 may be used in material processing to rapidly heat or ablate a portion of a material being processed, or to induce a photo-chemical process. Alternatively, coupler 40 may be used in a photography application to provide a flash for picture taking. Using such a coupler would allow the flash bulb to be located inside the camera, with the light transmitted to outside the camera using an optical fibre. As one skilled in the art should recognise coupler 40 allows the use of incoherent light in many applications that coherent or incoherent light has been used in the past.

To provide for coupling the light to an optical fibre, flash tube 42 has a toroidal shape, shown in Figures 5 and 6, and is disposed inside reflector 44. In addition to the toroidal shape other shapes, such as a continuous helix, may be used for flash tube 42. However, a helical tube is more difficult to manufacture than a toroidal tube. Referring now to Figure 6, flash tube 42 is generally in the shape of a torus, but is not a perfect torus since the electrodes located at the end of the torus have to be connected to the power source. This does not create a significant disturbance in the circular shape of flash tube 42, since the connection to the electrodes can be made quite small.

Reflector 44 collects and concentrates the light, and has a cross-section of substantially an ellipse, in

a plane perpendicular to the minor axis of the toroidal flash tube 42. The major axis of this ellipse preferably forms a small angle with the major axis of toroidal lamp 42. The exact value of the angle between the ellipse axis and the main axis of lamp 42 depends on the Numerical Aperture (NA) of the optical fibre.

The toroidal flash tube is positioned so that its minor axis coincides with the focus of the ellipse. The other focus of the ellipse is at the edge of optical fibre 46. Reflector 44 may be machined from metal with the inner surfaces polished for good reflectivity. Aluminum is a very good reflector with high reflectivity in the visible and ultraviolet, and it may be used for this purpose. The reflector can be machined in one piece and then cut along a surface perpendicular to the main axis of the device. This will enable integration of the toroidal flash tube into the device.

As shown in Figure 4, the edge of optical fibre 46 is a cone with a small opening angle, so that the total area of the fibre exposed to the light from the flash tube is increased. Referring now to Figure 7 the geometry for coupling light into a conical tip is shown. It is assumed here that the light comes from a region in space with a refractive index of n_2 and that the conical section of the fibre (as well as the rest of the fibre core) has a refractive index of n_1 .

Not all the light rays hitting the cone are trapped in it. For light rays that propagate in a plane that contains the major axis of the system, a condition can be derived for the angle of a ray that will be trapped and absorbed in the fibre. This condition is shown in Equation 3.

$$\sin(\mu_{\text{crit}}) = \cos(\beta) - (n_1^2/n_2^2 - 1)^{1/2} \sin(\beta) \quad (\text{Eq. 3})$$

Light will be trapped in the conical portion of the optical fibre if the incidence angle μ is larger than μ_{crit} calculated from Equation 3. Trapping is possible only if $n_1 > n_2$. If the medium outside of the fibre is air, $n_2 = 1$. Not all of the light trapped in the conical section of the fibre will also be trapped in the straight portion of the fibre if a fibre with a core and a cladding is used. If a fibre with a core and no cladding is used (air cladding), then all the rays captured in the conical section of the fibre will also be trapped in the straight section of the fibre.

The configuration shown in Figure 4 can also be used with a fluid filling the volume between the reflector and the optical fibre. A very convenient fluid for this purpose may be water. Water is also very effective in cooling the flashlamp if high repetition rate pulses are used. The presence of a fluid reduces the losses that are associated with glass to air transitions, such as the transition between the flashlamp envelope material and air. If a fluid is used in the reflector volume, then its refractive index can be chosen such that all the rays trapped in the conical section are also trapped in the fibre, even if core/cladding fibres are used.

Another way of configuring the fibre in the reflector is by using a fibre with a flat edge. This configuration is shown in Figure 8 and has trapping efficiency very close to the trapping efficiency of the conical edge. Many other shapes of the fibre edge, such as spherical shapes, can also be used. The configuration of the fibre edge also has an effect on the distribution of the light on the exit side of the fibre and it can be chosen in accordance with the specific application of the device.

The device may be used with a variety of optical fibres. Single, or a small number of millimetre or sub-millimetre diameter fibres, will typically be used in invasive medical applications. In other applications, particularly in industrial and domestic applications, it may be preferable to use a fibre having a larger diameter, or a larger bundle of fibres, or a light guide.

Figures 9 and 10 show a coupler 90 for coupling a linear flash tube 92 through a linear to circular fibre transfer unit 94 to a fibre bundle 96. A reflector 98 has an elliptical cross-section, shown in Figure 10, in a plane parallel to the axis of linear flash tube 92 in this embodiment. Tube 92 is located on one focus of the ellipse while the linear side of linear to circular bundle converter 94 is located at the other focus of the ellipse. This configuration is relatively simple to manufacture and commercially available linear to circular converters such as 25-004-4 available from General Fibre Optics may be used. This configuration is particularly useful for larger exposure areas of the fibre, or for flash illumination purposes.

The energy and power densities that can be achieved by this invention are high enough to get the desired effects in surface treatment or medical applications. For the embodiment shown in Figure 4 the total energy and power densities can be estimated as follows. For a typical toroidal lamp with a 4mm bore diameter and a major diameter of 3.3cm an electrical linear energy density input of 10J/cm into the lamp can be used with a 5μsec pulse width. The light output of the lamp will be 5 to 6J/cm for optimal electrical operating conditions. For the reflector shown in Figure 4, 50% of the light generated in the lamp will reach the lower focus. Thus, a total energy flux on the focus of 25 to 30J may be obtained. For embodiments shown in Figure 4 or Figure 8 the total cross-section area of reflector at the focal plane has a cross-section of 0.8cm².

Energy densities on the order of 30 to 40J/cm² at the entrance to the fibre should be attained with this cross-section. This corresponds to power densities of 5 to 10MW/cm², which are the typical power densities used in medical or material processing applications.

For longer pulses, higher linear electrical energy densities into the lamp can be used. For a 1msec pulse to the flash tube a linear electrical energy density of 100J/cm can be used. The corresponding energy density at the focal area would be up to

300J/cm². Such energy densities are very effective in industrial cleaning and processing applications as well as in medical applications.

Alternative embodiments for coupling the optical fibre to an extended light source such as a linear flashlamp are shown in Figures 11 and 12. In the embodiment of Figure 11 an optical fibre 101 is wound around a lamp 102 and a lamp envelope 103. Some of the light that is produced by the light source is coupled into the fibre. If the light rays are propagating in the direction that is trapped by the fibre then this light will propagate in the fibre and it can be used at a fibre output 104. One limitation of this configuration is the fact that most of the light emitted by lamp 103 travels in a direction perpendicular to the surface of lamp 103 and cannot be trapped in fibre 101.

The embodiment shown in Figure 12 overcomes this problem. A doped optical fibre 105 is wound around lamp 102 and envelope 103, rather than an undoped fibre such as fibre 101 of Figure 11. The dopant is a fluorescent material which is excited by the radiation emanating from lamp 102 and radiates light inside the fibre. This light is radiated omnidirectionally and the part of it that is within the critical angle of fibre 105 is trapped and propagates through the fibre and can be used at fibre output 104. The angle of light that is trapped in the fibre is the critical angle of the material from which the optical fibre or optical wave guide is made. For a fibre (or optical wave guide) in air this angle is given by $\sin \alpha = 1/n$.

Typically for glass or other transparent materials $n = 1.5$ and $\alpha = 41.8^\circ$. This corresponds to a trapping efficiency of more than 10% of the light emitted by fluorescence inside the fibre. If we assume a 50% efficiency of the fluorescence process we find out that more than 5% of the light produced by the lamp is trapped and propagated down the fibre. For example, a 4" (10.2cm) lamp with a linear electrical energy input of 300J/inch (118 J/cm) and 50% electrical to light conversion efficiency would couple 2.5% of its electrical energy into the fibre. This corresponds, for the 4" (10.2cm) lamp case to a total light energy of 30J of light. This embodiment has the additional advantage of transferring the wavelength emitted by the lamp to a wavelength that may be more useful in some of the therapeutic or processing applications mentioned before. Thus, fluorescent material doped in the fibre can be chosen in accordance with an emission wavelength determined by the specific application of the device.

Thus, it should be apparent that there has been provided in accordance with the present invention a flashlamp and coupler that fully satisfy the objectives and advantages set forth above. Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to

embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

Claims

1. A therapeutic treatment device characterised in that an incoherent light source (14) is operable to provide a pulsed light output for treatment.
2. A treatment device as claimed in claim 1 further characterised in that a variable pulse width pulse forming circuit is electrically connected to said light source.
3. A treatment device as claimed in any one of the preceding claims, further characterised in that said light source is a flashlamp (14).
4. A treatment device as claimed in any one of the preceding claims, further characterised in that said light source comprises means for providing pulses having a width in the range of between substantially 0.5 and 10 microsec and an energy density of the light on the skin of up to about 10J/cm², whereby the light treats external disorders of the skin, such as: tattoos, pigmented lesions or birth and age marks.
5. A treatment device as claimed in any one of the preceding claims, further characterised in that said light source (14) is mounted in a housing (12) suitable for being disposed adjacent a skin treatment area, said housing having a reflector (16) mounted therein proximate said light source, and said housing having an opening, with an iris (20) mounted about said opening, and at least one optical filter (18) mounted proximate said opening.
6. A treatment device as claimed in claim 5, further characterised in that a means (18) for providing controlled energy density, filtered, pulsed light output through said opening and said iris to a skin area for treatment is provided.
7. A treatment device as claimed in claim 5 or 6, further characterised in that a power supply is connected to and external of said housing, wherein said housing includes a handle (13).
8. A device as claimed in any one of the preceding claims, further characterised in that a plurality of optical fibres (96), each having an end disposed within a reflector (98) and a linear to circular fibre transfer unit (94) is disposed to receive light from the light source (92) and provide light to the opt-

ical fibres.

9. A device as claimed in claim 8, wherein a reflector (98) has an elliptical cross-section in a plane parallel to the axis of a light source which comprises a linear flash tube (92), and wherein the linear flash tube is located at one focus of the ellipse while the linear to circular transfer unit (94) is located at the other focus of the ellipse. 5 10
10. A system for providing pulsed light characterised in that:
a pulsed toroidal flash tube incoherent light source (42, 92) has a reflector (44) disposed thereabout, said reflector having a cross-section of substantially an ellipse, in a plane perpendicular to the minor axis of the toroidal flash tube; and at least one optical fibre (46) having an end disposed within said reflector. 15 20
11. A system as claimed in claim 10, further characterised in that the end of the optical fibre has a cone shape. 25
12. A system as claimed in claim 10, further characterised in that the end of the optical fibre is flat.
13. A system as claimed in any one of claims 10 to 12, further characterised in that the optical fibre is air clad. 30

35

40

45

50

55

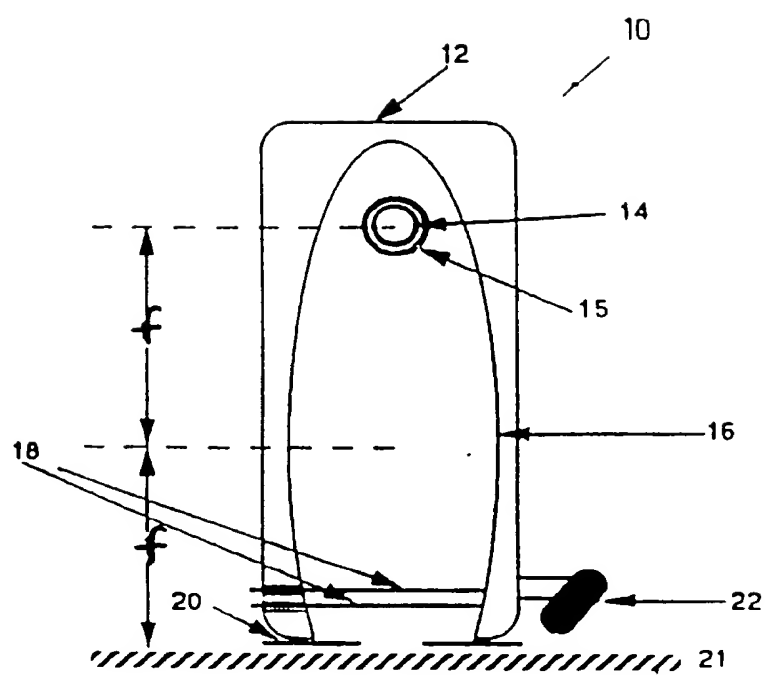


Figure 1

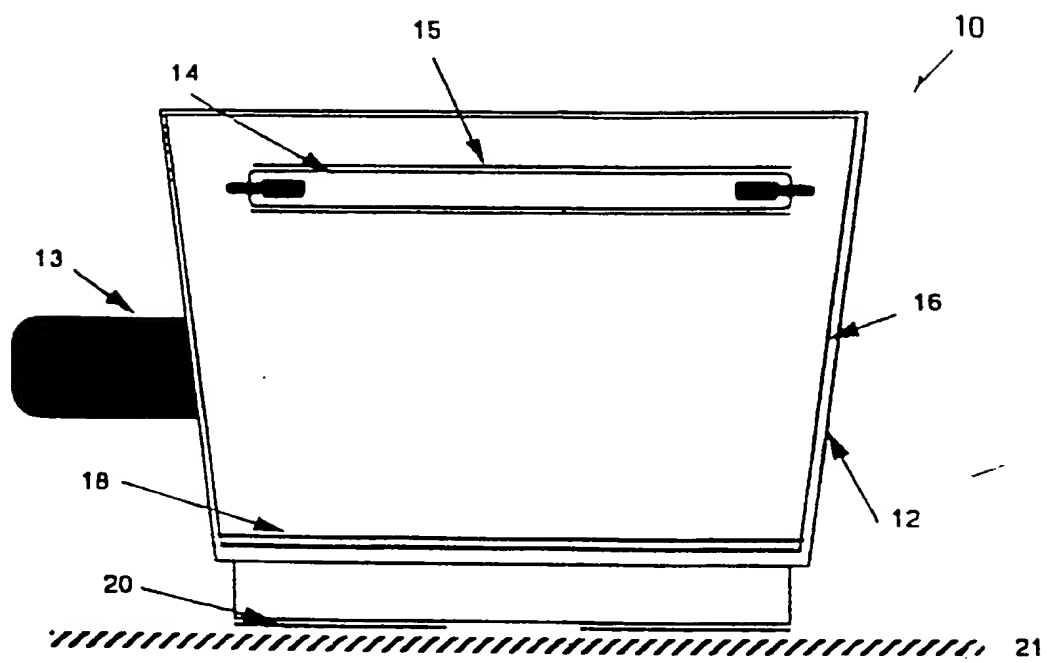


Figure 2

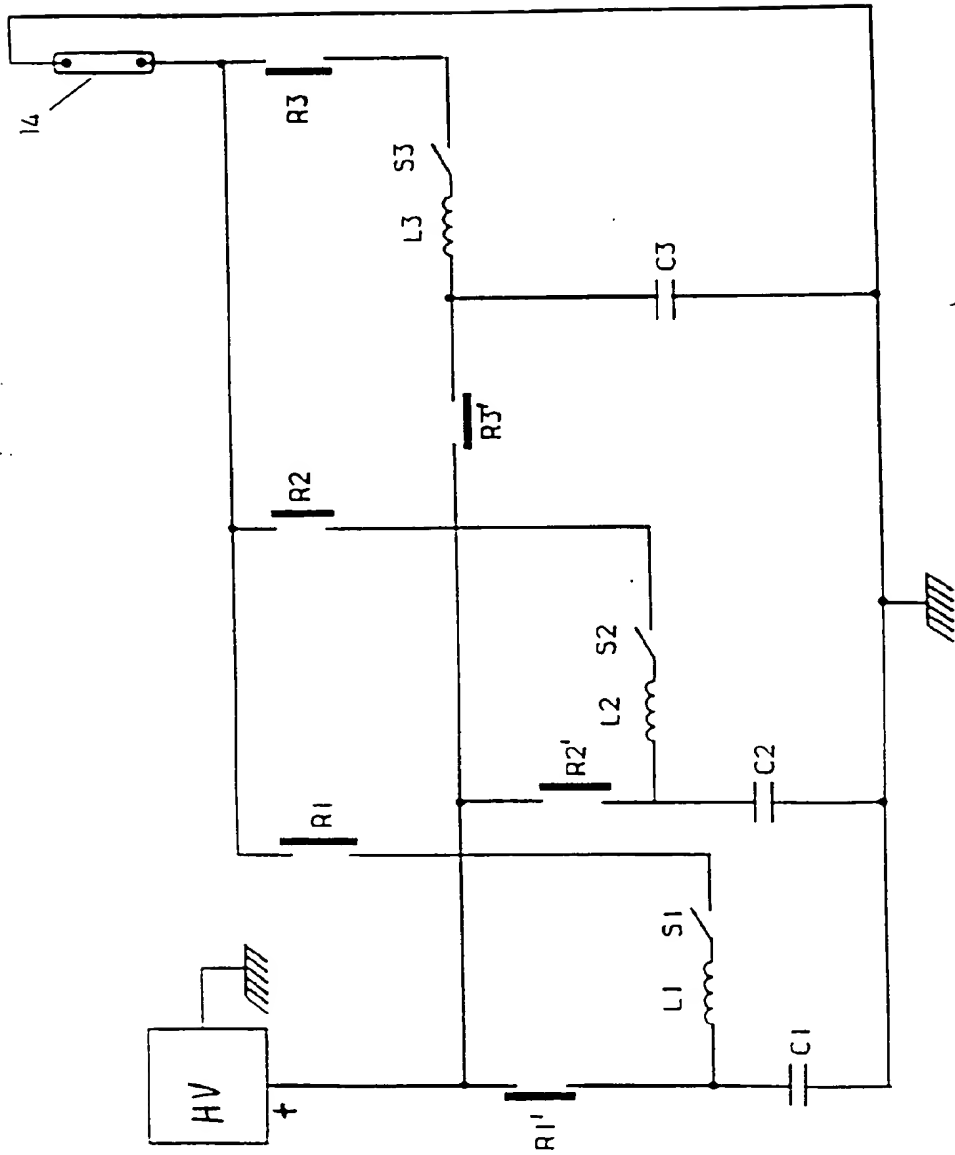


Figure 3

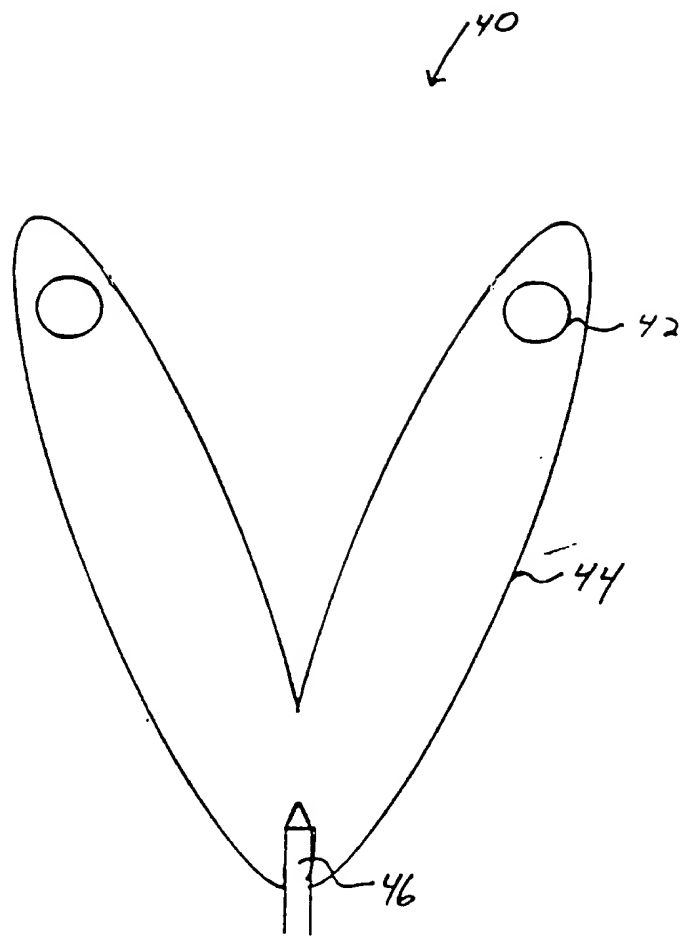


Figure 4

Figure 5

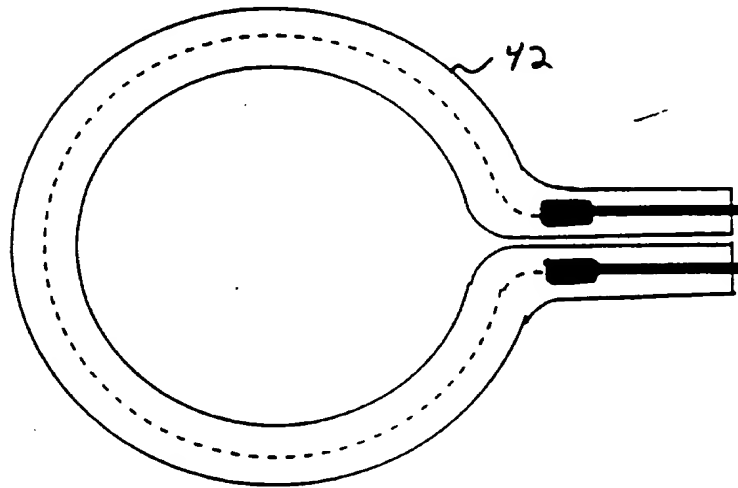
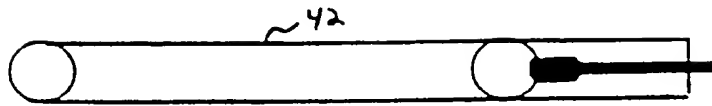


Figure 6

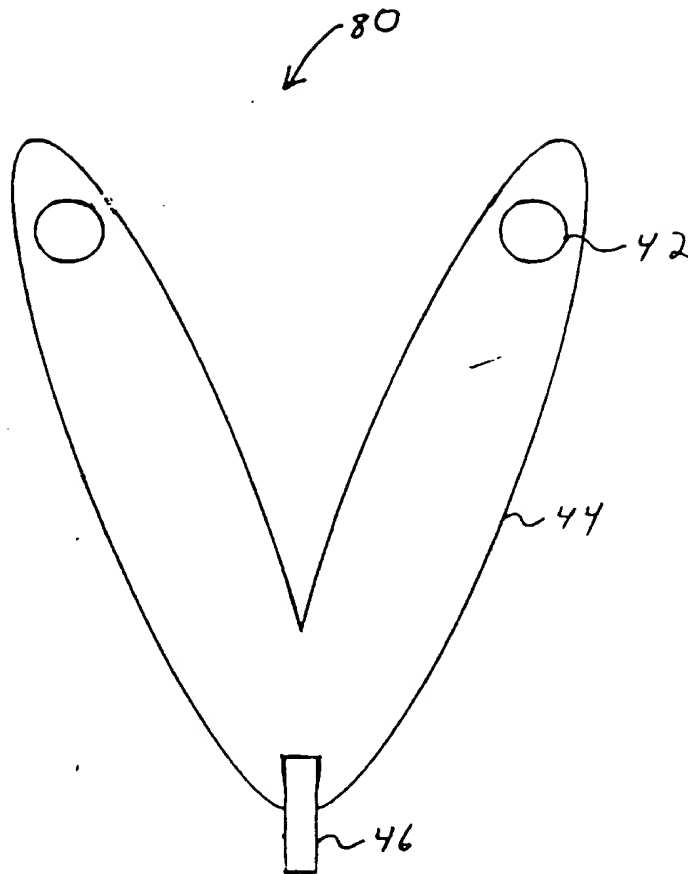


Figure 8

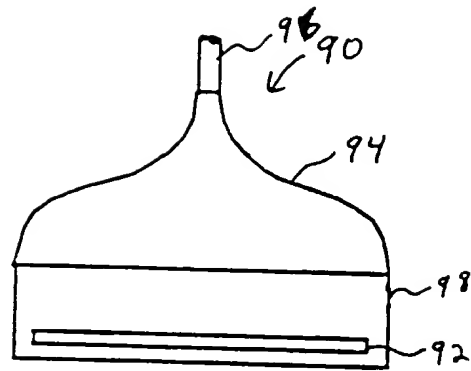


Figure 9

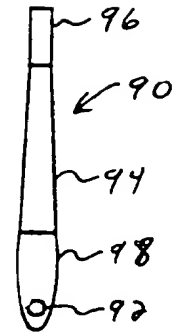


Figure 10

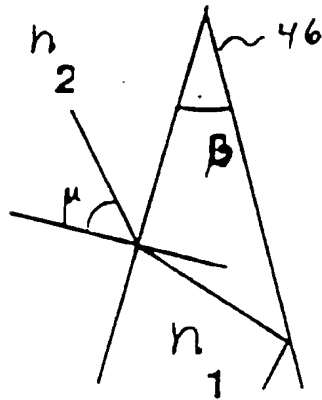


Figure 7

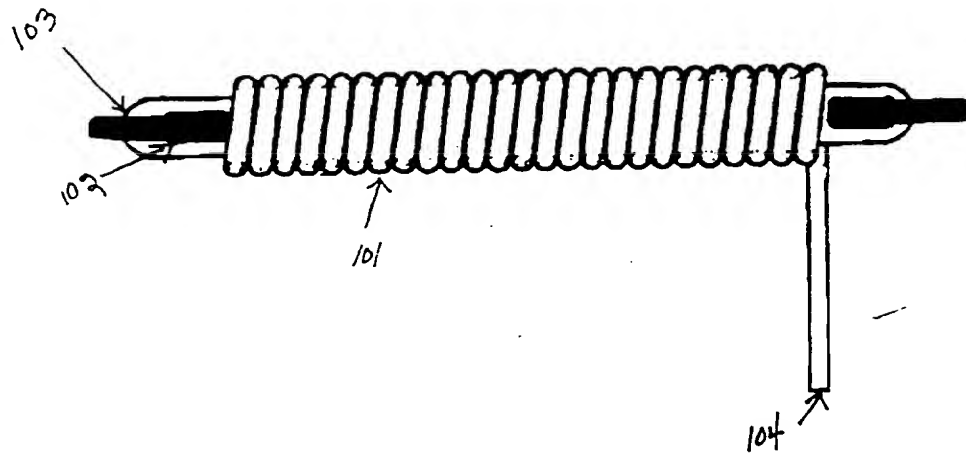


Figure 11

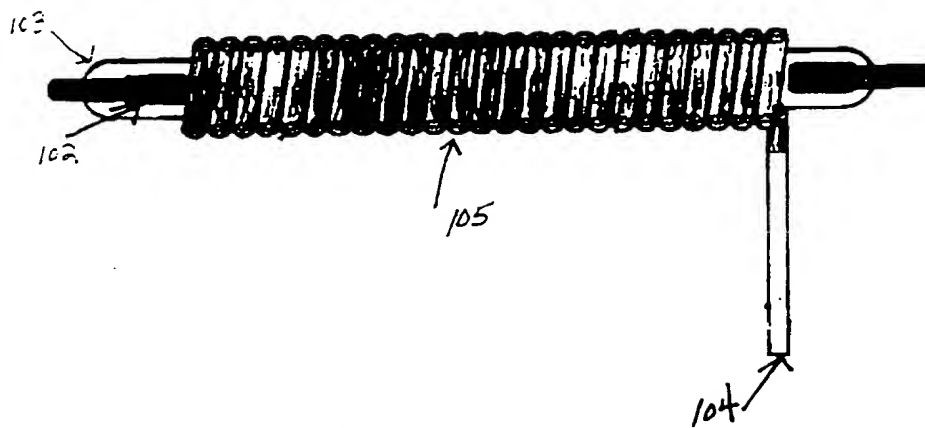


Figure 12



Publication number : **0 565 331 A3**

⑫

EUROPEAN PATENT APPLICATION

⑪ Application number : **93302662.7**

⑤ Int. Cl.⁵ : **A61N 5/06**

⑫ Date of filing : **05.04.93**

③ Priority : **09.04.92 IL 101547**
20.10.92 US 964210

④ Date of publication of application :
13.10.93 Bulletin 93/41

⑧ Designated Contracting States :
AT BE CH DE DK ES FR GB GR IE IT LI LU MC
NL PT SE

⑧ Date of deferred publication of search report :
28.12.94 Bulletin 94/52

⑦ Applicant : **ESC Inc**
329 Central Street
Newton, Massachusetts, 02166 (US)

⑦ Inventor : **Eckhouse, Shimon**
27 Ester-Rabin Street
Haifa 34987 (IL)

⑦ Representative : **Cookson, Barbara Elizabeth**
et al
Titmuss Sainer & Webb,
2 Serjeants' Inn
London EC4Y 1LT (GB)

⑤ Therapeutic electromagnetic treatment.

⑤ A therapeutic treatment device is disclosed and includes a housing (12) and an incoherent light source (14) such as a flashlamp disposed in the housing. The flashlamp provides a pulsed light output for treatment of external skin disorders. To provide light to the treatment area the housing has an opening that is disposed adjacent a skin treatment area. A reflector (16) is mounted within the housing near the light source to reflect the light to the treatment area. At least one optical filter (18) and an iris (20) are mounted near the opening in the housing. Power to the lamp is provided by a pulse forming circuit that can provide a variable pulse width.

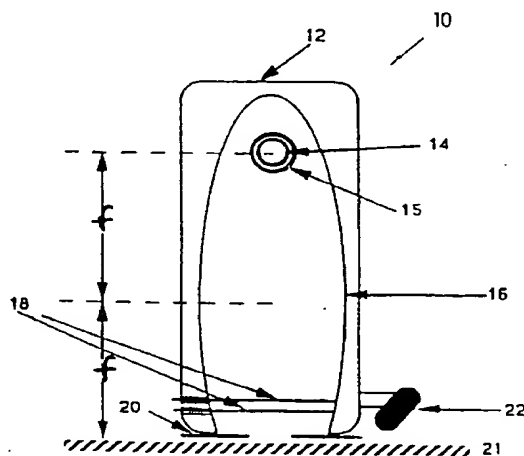


Figure 1

EP 0 565 331 A3



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 30 2662

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
X	WO-A-91 15264 (GUSTAFSSON) * page 2, line 18 - page 4, line 20; figures 1,2 *	1	A61N5/06
A	---	2-4,6	
A	PATENT ABSTRACTS OF JAPAN vol. 4, no. 172 (P-038) 9 September 1980 & JP-A-55 117 166 (USHIO INC) * abstract *	1,3,10	
A	---		
A	CH-A-416 861 (KERN & SPRENGER) * page 2, column 70 - column 105; figure 2 *	1,5,6	
A	---		
A	EP-A-0 052 765 (MUTZHAS) * page 9, line 18 - page 10, line 7; figure 1 *	1,5,6	
A	---		
A	US-A-1 651 385 (GOODRICH) * page 1, line 45 - page 2, line 68; figures 1-4 *	1,5,7	
A	---		
A	DE-A-27 17 421 (NATH) * page 10, line 22 - page 12, line 15; figure 1 *	1,2,5,7, 9,12	A61N
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 28 October 1994	Examiner Herbelet, J.C.
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : number of the same patent family, corresponding document			

EPO FORM 1500 (01.92) (P.O. 08/91)